

FOODSTUFFS AND MEDICINES AS LEGAL CATEGORIES IN THE EU AND CHINA

FUNCTIONAL FOODS AS A BORDERLINE CASE

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I dedicate this book to my daughter Mimosa who wants to be a painter or a dancer when she grows up. Follow your dreams, whatever they may be!

Eurajoki 21st October 2009



Anu Lähteenmäki-Uutela



Abstract

The thesis discusses the regulation of foodstuffs and medicines, and particularly the regulation of functional foods. Legal systems investigated are the EU and China. Both are members of the WTO and Codex Alimentarius, which binds European and Chinese rules together. The study uses three Chinese berries as case examples of how product development faces regulation in practice. The berries have traditional uses as herbal medicines. Europe and China have similar nutrition problems to be resolved, such as obesity, cardiovascular disease, and diabetes. The three berries might be suitable raw materials for functional foods. Consumer products with health-enhancing functions, such as lowering blood pressure, might legally be classified either as foodstuffs or medicines. The classification will depend on functions and presentation of the product. In our opinion, food and medicine regulation should come closer together so the classification issue would no longer be an issue.

Safety of both foodstuffs and medicines is strictly regulated. With medicines, safety is a more relative concept, where benefits of the product are compared to side-effects in thorough scientific tests and trials. Foods, on the other hand, are not allowed to have side-effects. Hygiene rules and rules on the use of chemicals apply. In China, food safety is currently at focus as China has had several severe food scandals. Newly developed foods are called novel foods, and are specifically regulated. The current European novel food regulation from 1997 treats traditional third country products as novel. The Chinese regulation of 2007 also defines novel foods as something unfamiliar to a Chinese consumer. The concepts of novel food thus serve a protectionist purpose.

As regards marketing, foods are allowed to bear health claims, whereas medicines bear medicinal claims. The separation is legally strict: foods are not to be presented as having medicinal functions. European nutrition and health claim regulation exists since 2006. China also has its regulation on health foods, listing the permitted claims and how to substantiate them. Health claims are allowed only on health foods. The European rules on medicines include separate categories for herbal medicines, traditional herbal medicines, and homeopathic medicines, where there are differing requirements for scientific substantiation. The scientific and political grounds for the separate categories provoke criticism.

At surface, the Chinese legal system seems similar to the European one. To facilitate trade, China has enacted modern laws. Laws are needed as the country moves from planned economy to market economy: 'rule of law' needs to replace 'rule of man'. Instead of being citizens, Chinese people long were subordinates to the Emperor. Confucius himself advised to avoid conflict. Still, Chinese people do not and cannot always trust the legal system, as laws are enforced in an inconsistent manner, and courts are weak. In China, there have been

problems with conflicting national and local laws. In Europe, the competence of the EU vs. the competence of the Member States is still not resolved, even though the European Commission often states that free trade requires harmonisation.

Food and medicine regulation is created by international organisations, food and medicine control agencies, standards agencies, companies and their organisations. Regulation can be divided in 'hard law' and 'soft law'. One might claim that hard law is in crisis, as soft law is gaining importance. If law is out of fashion, regulation certainly isn't. In the future, 'law' might mean a process where rules and incentives are created by states, NGOs, companies, consumers, and other stakeholders. 'Law' might thus refer to a constant negotiation between public and private actors. Legal principles such as transparency, equal treatment, and the right to be heard would still be important.

Abbreviations

ACE	Angiotensin-Converting Enzyme
AIDS	Acquired Immune Deficiency Syndrome
ALDE	Alliance of Liberals and Democrats for EU
ANH	Alliance for Natural Health
AQSIQ	Administration for Quality Supervision and Inspection and Quarantine (China)
ASEAN	Association of Southeast Asian Nations
BEUC	Bureau Européen des Unions de Consommateurs (the European Consumers' Association)
BMI	Body mass index
BSE	Bovine Spongiform Encephalopathy
CAM	Complementary and alternative medicine
CCCD	China Certification Committee for Drugs
CEN	Comité Européen de Normalisation. European Committee for Standardisation.
CENELEC	Comité Européen de Normalisation Electrotechnique. European Committee for Electrotechnical Standardization.
CHMP	Committee for Human Medicinal Products (EMA)
CIAA	Confederation of the Food and Drink Industries in the EU
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COMP	Committee on Orphan Medicinal Products (EMA)
CTD	Common Technical Document (medicine law)
CVD	Cardiovascular disease
DG SANCO	Directorate General on Health and Consumer Protection (European Commission)
DNA	Deoxyribonucleic acid
EAS	European Advisory Services (company)
EC	European Community
ECJ	European Court of Justice
EEC	European Economic Community
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPHA	European Public Health Alliance
EPP	European People's Party
ERNA	European Responsible Nutrition Alliance
ESO	European Standards Organisation
ESSNA	European Specialist Sports Nutrition Alliance
ETSI	European Telecommunications Standards Institute
EU	European Union
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration (US)
FSA	Food Standard Agency (UK)
FUFOSE	European Commission Concerted Action on Functional Food Science in Europe
FVO	Food and Veterinary Office (European Commission)

GATS	General Agreements on Trade in Services (WTO)
GATT	General Agreement on Tariffs and Trade (WTO)
GCMP	Good Chinese Medicine Production Practice
GDA	Guideline Daily Amount
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GSP	Good Sales Practice
HACCP	Hazard Analysis and Critical Control Points
HDL	High-density lipoprotein
HIV	Human immunodeficiency virus
HMPC	Committee on Herbal Medicinal Products (EMEA)
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ILSI	International Life Sciences Institute
ISO	International Organization for Standardisation
KFC	Kentucky Fried Chicken (company)
LACOTS	Local Authority Co-ordinating Body on Trading Standards (UK)
LDL	Low-density lipoprotein
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
MOA	Ministry of Agriculture (China)
MOFTEC	Ministry of Foreign Trade and Economic Cooperation (China)
MOH	Ministry of Health (China)
MOST	Ministry of Science and Technology (China)
MRL	Maximum residue level
MT	Markkinatuomioistuin (Finland)
NAM	National Agency for Medicines (Finland)
NGO	Non-governmental organization
NPC	National People's Congress (China)
NSB	National Standards Body
OECD	Organisation for Economic Cooperation and Development
OTC	Over-the-counter
PAG/UNU	Protein Advisory Group of the United Nations
PDCO	Committee on Paediatric Medicinal Products (EMEA)
PES	Party of European Socialists
RNA	Ribonucleic acid
SDA	State Drug Administration (China)
SFDA	State Food and Drug Administration (China)
SMEs	Small and medium sized enterprises
SPC	Summary of Product Characteristics (medicine law)
SPC	Supreme People's Court (China)
SPS	Sanitary and Phytosanitary Measures (WTO agreement)
TBT	Technical Barriers to Trade (WTO agreement)
TCM	Traditional Chinese Medicine
TRIPs	Trade-Related Aspects of Intellectual Property Rights (WTO agreement)
UCP	Unfair commercial practices (EU directive)
WHO	World Health Organization
WTO	World Trade Organization

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¹ The very basic rules on European food and medicine law that are often relevant to a developer of functional foods.

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1 INTRODUCTION

1.1 The Role of Functional Foods in Modern Diets

Today, many people are voluntarily engaging in unhealthy diets consisting of too much energy, fat, salt, and sugar. This, together with insufficient physical exercise, is causing a profusion of diet-related illnesses, which in turn cause much human suffering and significant expenditure. Europe and China face similar problems in this respect. Because these problems are continually discussed in the media, consumers are increasingly aware of *the diet-health relationship*.¹ In the past, dietary advice has often focused on what not to eat. Currently, the focus is on what should be eaten more. There is an abundance of foods on the market that are consumed in order to improve one's health in general or in a particular manner.

'*Functional foods*' is the term used for foods with special health effects.² Interest in functional foods is stimulated by several factors. There is a market push from food companies looking for products with higher margins. A plethora of private research resources are invested in functional foods. Clinical studies are being performed world-wide to show effects of new foods or food ingredients. Functional attributes of many traditional foods are being discovered, and new products are being developed with beneficial components³. Market pull is created by aging, affluent populations of health conscious consumers.⁴

In addition to companies and consumers, functional foods are interesting also from a governments' perspective. The main severe health challenges in Western countries are obesity, cardiovascular disease, diabetes, and cancer. Healthcare costs are increasing, and the prevalence of all of these diseases can be affected by dietary choices. Heart conditions and diabetes, along with the acceptance of Western-like diets have also become more common in Asia. This means the diet-related health problems are largely the same all over the world and different governments are faced with the almost identical task of promoting the same kind of dietary change. Public research funds are liberally invested in functional foods to support private research efforts.

¹ This awareness as such is nothing new. For example Hippocrates said in 337 BC "Let food be your medicine and medicine be your food". This wisdom is now being rediscovered in the West.

² There are different definitions of the term 'functional food', and related terms referring to similar products. In chapter 1.3., we present the different definitions and define the term 'functional food' for our purposes.

³ International Food Information Council. Functional Foods. Background. November 2007.

⁴ Katan 1999, 1.

1.2 Law on Functional Foods

Legislation on functional foods has not developed as quickly as functional foods. It is typical that legal development follows scientific development. Compared to discussing the legal definitions, scientists are more interested in developing effective products, and marketers more interested in finding attractive marketing messages. Consumers need time to become acquainted with new types of products.⁵ It has been acknowledged that legal definitions and rules on product safety and efficacy are needed for consumers to trust the products and the markets to develop. *New legislation* has been shown to be necessary. The wrong type of legislation, confusing legislation or non-existing legislation might discourage firms from investing in safety assessment and research.⁶ This could lead to a situation where:

- the food industry lacks innovative and successful products to compete with,
- consumers do not get the product selection they are willing to pay for, and
- populations are not as healthy as they could be.⁷

Currently no legal definitions exist for functional foods. Health claim legislation can be seen as indirectly defining functional foods, though. According to Heasman and Mellentin, the exceptional speed of internationally agreeing on the need of health claim legislation shows the power of the functional food concept⁸. For example, United States, Japanese, and Chinese legislation developed quite quickly after the functional food business started to grow. Health claim standards were developed by Codex Alimentarius already in the beginning of the 21st century. Similarly, some European states like Sweden, the Netherlands, and the UK, regulated functional foods and health claims early on. States in southern Europe, conversely, were in no rush to regulate. The European disagreement on the need, purpose, and content of common legislation led to lengthy negotiations, before nutrition and health claim legislation finally came into effect in 2007.

The basic legal question with functional foods is *the division between foodstuffs and medicinal products*. In Europe, foods and medicines were traditionally separate legal categories. Food safety fundamentally signified hygiene rules and safety evaluations concerning the use of chemicals. It was not a problem that marketing claims relating to diseases were prohibited on foodstuffs. In the Eastern countries influenced by Chinese culture, food and medicines have traditionally been thought of as materials from the same source, not something separate. For example, a plant can be used as food for healthy people and as medicine for people who are sick. It is thus not a Western invention

⁵ See also Kwak – Jukes 2000a, 101.

⁶ Salminen – Mykkänen 2002, 33. See also Kotler 2002, 174-175. The legal issues are something a food marketer wants to consider already at the product development phase. It is not clever to develop a product with a focus on a certain planned marketing strategy only to find out that such a product is not even allowed, or that the planned marketing claim is prohibited.

⁷ According to Brookes, this is exactly what has happened with regard to novel foods and their regulation in Europe. R&D expenditure on food products tends to be lower in the EU compared to average levels in other countries. As a result, improved products are not available to EU consumers. Levels of income and employment generation in the EU are, according to Brookes, “probably” lower than in more “innovation-friendly” regulatory environments. Brookes 2007, 6.

⁸ Heasman – Mellentin 2001, 104.

and not simply a current phenomenon that the categories of food and drugs can sometimes overlap; merely functional foods make this overlap more obvious.

Regulating safety and efficacy of consumer products is basic *consumer protection law*. Consumer protection law can be divided into product safety, contract terms, marketing, and product liability⁹. Here we deal with two of these areas: *product safety* and *marketing*. Product safety is defined as *physical safety, protecting the consumer's body*. Safety is a relative term referring to absence of negative health effects. Efficacy is used as a term related to marketing claims of the product. Efficacy means that the product delivers the health-benefit it promises. The basic goal of marketing regulation is *economic safety - protecting the consumer's purse*¹⁰. This means marketing rules may also be seen as part of product safety.

The regulation of medicines and the regulation of foods have important features in common. Both groups of products are used in a way that leads to a potential risk to consumers¹¹. Costs of inadequate information are severe, and yet the markets do not accord information its full value¹². Consumers usually cannot see the ingredients, qualities, or functions of a foodstuff or a medicine just by looking at the product. Even if all the scientific information was available to consumers, they still could not determine the potential risks or benefits for their health. This significant information asymmetry creates the need for regulation¹³. With foodstuffs and medicines, consumer protection laws are widely accepted because of these information difficulties¹⁴. However, even if we agree on the necessity to regulate food and medicine businesses, particular policies are still not free from controversy¹⁵. For example, insistence on safe medicines and functional foods may prevent useful but slightly risky substances from reaching the market¹⁶.

Procedural rules are also important as they define how substantial rules are implemented in practice. When implementing safety and efficacy requirements, the legislator must decide whether to rely on *pre-market control* or *post-market control*. Pre-market authorisation is often preferred today. Innovative functional foods must be authorised in both the EU and China before being marketed to consumers.

Legislators must also resolve the appropriate level and type of regulations. When discussing the level of regulation, all of the above-mentioned issues can be resolved either on *local or global level*. Both the European Community and China are members of WTO and other international organisations where food and drug law issues are discussed. On one hand, global agreements guide legislative actions of their parties. On the other hand, through global negotiations it is possible for the EU and China to affect global legal development. In the EU, Community level legislation is

⁹ Wilhelmsson (1991) divides consumer protection into protection against: dangerous products (product safety and product liability), unreasonable contract terms, inappropriate marketing and unconsidered decision-making. Kivivuori et al. (1978) divide consumer policy into four areas according to stages of the product life cycle: production, marketing, trade, and consumption.

¹⁰ Besides consumer protection, marketing regulation is particularly important also from competitor point of view.

¹¹ Krapohl 2004, 519.

¹² Asch 1988, 55.

¹³ Krapohl 2004, 521. According to Määttä, information asymmetry is one of the basic reasons for consumer protection laws. Määttä 2006, 22.

¹⁴ Asch 1988, 55.

¹⁵ Asch 1988, 55.

¹⁶ Asch 1988, 56.

today often preferred to legislation on Member State level. Likewise in China, national laws are preferred to local laws.

With regard to the types of regulation, the issues can be resolved either by *legally binding or non-binding instruments*. Governments need to consider their role in relation to other regulators such as governmental and non-governmental organisations. Soft law has many definitions, but it essentially means regulations that are not laws¹⁷. The binding nature of soft law materials will be an unresolved issue. These guideline-type norms are often considered suitable for regulating foodstuffs and medicines. This is due to the amount of scientific issues, the need for complex procedures, the need for rapid changes, and the need for some flexibility in interpreting these complex issues. Soft law is mainly created by food and medicine control agencies. This means implementing the law actually includes creating the law. Also self-regulation by enterprises themselves has its limited space.

1.3 Basic Definitions Used in this Study

Legally, the definitions of ‘foodstuff’ and ‘medicine’ exclude one another. If a product is a medicine, it is not a food.

‘*Foodstuff*’ or ‘*food*’ means any edible product suitable for people in general or for a certain group of people. This includes foods in food form and in other forms such as pills, capsules, powders, etc.

‘*Medicine*’ is synonymous with drug¹⁸. It means a product that is used to treat, prevent, or cure a disease. This includes modern medicines (pharmaceuticals), and traditional medicines, which in practice are often herbal medicines.

The third significant term used in this study, ‘functional food’, is more difficult to define. As the laws do not define the concept, we have to use our own definition to suit our purposes.

Globally, there are many different definitions of the term ‘functional food’. ‘Functional food’ often refers to products that are in food form, whereas the term ‘nutraceutical’ often refers to products isolated or purified from foods.¹⁹ Both are generally understood as products demonstrated to have physiological benefits and/or to reduce the risk of chronic disease beyond basic nutritional functions. Functional foods can be understood either as finished food products or health-enhancing dietary components or ingredients.

It is not clear what ‘beyond basic nutrition’ means. According to Agriculture and agri-food Canada, this means that there are so-called “bioactive compounds” involved²⁰. Bioactive compounds are “naturally occurring chemical compounds contained in, or derived from, a plant, animal or marine source”, that exert the desired health/wellness benefit. They mention omega-3 fatty acids in fish oils and beta-glucan in oats and barley. According to Kris-Etherton et al, bioactive compounds are extranutritional constituents that typically occur in small

¹⁷ Tala 2005a. Korkea-aho 2005.

¹⁸ ‘Drug’ could also be defined to mean any chemical other than food that affects living processes. By this definition, a drug could either be a ‘medicine’ or a ‘poison’. University of Elmhurst web page.

¹⁹ The term ‘medicinal food’ is also used, often to include food-form and pill-form foods. See for example *Journal of Medicinal Foods*.

²⁰ Agriculture and agri-food Canada. What are Functional Foods and Nutraceuticals?

quantities in foods²¹. They mention for example phenolic compounds, including flavonoids as their subcategory, and recommend consuming foods rich in bioactive compounds.

Different layers of functional foods can be identified. There are fresh foods such as carrot and tomato that have functional effects²² basic processed foods such as rye bread, oat bran cereal, and yogurt that have functional effects²³ and fortified foods where certain nutritional ingredients are added²⁴. In addition there are foods traditionally propagated or genetically engineered to have more of a functional component²⁵.²⁶ Heasman and Mellentin²⁷ use the definition ‘any *modified* food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains’. They do not include ‘natural’ functional foods in their definition.

Diplock et al.²⁸ proposed, as a working definition, that a food can be regarded as ‘functional’, “if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease.” It is also required that functional foods:

- a) remain as foods²⁹,
- b) demonstrate their effects in amounts that can normally be expected to be consumed in the diet, and
- c) are consumed as part of a normal food pattern.

Because functional food is not a legal term in the EU or China, *the aforementioned definitions have no legal relevance*. The legal rules on products are based on other concepts such as ‘food’, ‘health food’, ‘novel food’, ‘medicine’, ‘herbal medicine’, ‘traditional herbal medicine’, and ‘traditional Chinese medicine’. The definition of functional foods by Diplock et al. seems to have transferred into principles that are used in health claim legislation.

In this study, we use the term functional food to describe a certain type of product, the legal treatment of which we are interested:

- A functional food is a *final product* in any digestible form (food, pill, capsule, powder, etc.)
- A functional food might be *fortified* (unfamiliar ingredients added), possibly with novel ingredients, possibly genetically engineered.
- A functional food has *beneficial health effects*, which are either traditionally or scientifically established.

²¹ Kris-Etherton et al. 2002.

²² Carrots have carotene. Tomatoes have lycopene.

²³ Oats has beta-glucan (fibre). Rye has lignans (fibre). Yogurt has beneficial bacteria such as lactic acid bacteria.

²⁴ Vitamins and minerals such as calcium or magnesium are commonly added to several foods. For example plant sterols (phytosterols), plant stanols (phytostanols) and probiotics are also commonly added to foods where they normally are not present.

²⁵ For example tomatoes with higher levels of lycopene.

²⁶ Categories by Agriculture and agri-food Canada. The Leatherhead Functional food report from 2006 identifies two basic layers of functional foods from the marketing perspective, the health claim being the factor that separates ‘actual’ functional foods from ‘healthy foods’ merely perceived as functional.

²⁷ Heasman – Mellentin 2001, 5.

²⁸ Diplock et al. 1999, S6.

²⁹ This means food supplements do not go under this definition of functional foods.

Even though our concept 'functional food' includes the term 'food', we do not presuppose that a functional food is legally a foodstuff. Instead, we investigate the conditions on which a hypothetical product is legally a food and on which a medicine. The legal category will depend on product functions and on marketing claims used. We are particularly interested in the legal evaluation of healthy products made of three Chinese berries, which might in Europe be classified as ordinary foods, foods for particular nutritional use, or herbal medicines. In China, the products could possibly be registered as health foods or traditional Chinese medicines. The determination of legal category will affect the evidence required on safety and efficacy, and the marketing claims available.

1.4 Comparative Law: EU and China as Objects of Research

Comparative law means the study of legal systems by comparison with each other. According to editors of *Electronic Journal of Comparative Law*, "substantive comparative ... law topics will have to discuss and compare at least two legal systems"³⁰. The idea of the comparative approach is to collect information on several legal systems simultaneously, crossing national borders³¹. This is the simple and practical view to comparative law: if there are at least two legal systems under discussion, it is comparative law.

According to Aarnio, comparative law is interested in the norm itself: it is about describing the structure and content of norms in a foreign legal order³². Mikkola sees comparative law more as understanding legal frameworks, structures, and principles rather than concrete rules. Rules are important, but only in their connection.³³ Husa sees comparative legal research as explaining and evaluating *solutions* to certain *problems* within societies, and the reasons for differences in these solutions³⁴. Also according to Watson, comparative law does not mean merely defining what is similar and what is different between two or more legal systems: it is about understanding the nature and development of legal systems. This includes analysing *why* certain institutions have been created in a legal system, and understanding the historical connections between legal systems and legal rules.³⁵ Comparative law can also be seen as having various ambition levels. A researcher can merely describe foreign law as curiosity, or try to understand it as a phenomenon.³⁶

In recent years, comparative law has gained in practical importance. According to Norman³⁷, there are two reasons for this. The first is the increased globalisation of world trade, which involves the need to do business in unfamiliar legal systems. The second is the move towards global or regional harmonisation of laws. Before laws are harmonised, they have to be compared. Along with the trend, we have reached the comparative approach because of global trade. More particularly, we are interested in global trade of functional foods, and therefore

³⁰ In addition to substantive topics, methodological aspects of comparative law are discussed under comparative law. *Electronic Journal of Comparative Law*. About EJCL.

³¹ Husa 2009, 123.

³² Aarnio 1988, 50.

³³ Mikkola 2001, 2.

³⁴ Husa 1998, 15-16.

³⁵ Watson 1974, 6-7.

³⁶ See Huhtamäki 1993, 20.

³⁷ Norman 2007.

need to understand global rules and rules outside our own legal system. As Husa suggests, we try to examine, explain, and evaluate different legal solutions to the reasonably wide issue of *how to regulate functional foods*.

The legal systems investigated here are *the European Union legal system and the Chinese legal system*. Generally, results of comparative legal research can be used in legal policy and lawmaking, in jurisdiction, and in creating legal theories. Regardless of how results are used, comparative law widens knowledge base.³⁸ We primarily aim at providing information for *two audiences: businesses and regulators*³⁹. Initially, we will study existing and planned regulations as they interest a business operating in 2009. In addition, we will look at the law from a regulator's perspective, focusing on how regulation should be formulated in the future. This study is not comparative law in the history-oriented sense. We will only briefly discuss the issue of how and why the European and Chinese legal systems have developed so far. We will, however, consider the fundamental differences of the two legal systems as they affect our conclusions both from business viewpoint and from the regulator's viewpoint.

The *practical reason* for choosing the EU as object of research is because of our residency in the EU. The practical reason for choosing China is due to the University of Turku maintaining close connections with Chinese universities and researchers. In particular, the University of Turku⁴⁰ has a project with the University of Beijing where we ultimately aim to bring new functional food products to European and Chinese markets. We have chosen the three berries (hawthorn, barbaric wolfberry, and emblic leafflower) because they are objects of interest in this project. We are aware that for a European lawyer, the Chinese part of this study is the more difficult one. Hence, the goals need to be somewhat different regarding European vs. Chinese law. With Chinese law, the aim is to achieve an understanding, and with European law, the aim is to add to the understanding.

Legal systems can be divided in Western and non-Western systems, where Western systems are individual-centred and non-Western systems are community-centred. Western systems can be further divided in common law and Romano-Germanic civil law. Non-Western legal systems can be divided in religious (Islamic, Jewish, and Hindu law) and non-religious systems. Non-religious systems include Asian law and traditional law. Asian law relies on the Confucian principle of mediation and avoiding disputes, which means that courts and lawyers are not in a central role. Traditional law, which is typical of aboriginal people and tribes, relies on spiritual and supernatural forces.⁴¹ In this division, Chinese law is a member of the Asian family. There are also other classifications: some writers, for example, separate between Roman, German, and Scandinavian law.

Today, Chinese law shares many of the characteristics of the Romano-Germanic system. The legislation reflects a structural similarity to countries in the civil law family, and Chinese jurists value legal doctrines and hold written law in esteem. Concrete judicial decisions are not officially considered as a source of law.⁴² However, the Supreme People's Court is particularly

³⁸ Husa 1998, 14.

³⁹ Instead of legislator, we use the term regulator here to include bodies other than governments. These are the WTO, international standards bodies, administrative agencies, self-regulation associations, etc.

⁴⁰ Department of Biochemistry and Food Chemistry.

⁴¹ Husa 2009, 126-127.

⁴² This can be attributed to the Europeanization in China in the end of the 19th century and the beginning of the 20th century, and is also based on Chinese tradition: statutes or codes were highly valued already by the Qin Dynasty in 221-207 BC. Liu 2000.

influential in practice. Its decisions are factually used as a guideline in the practice of lower courts when the provision of law is obscure.⁴³ According to Jones, China has succumbed to Western arguments and built a European-style legal system, but has never been entirely convinced⁴⁴. The Chinese legal system is closely linked to the economy: China is still balancing between market economy and socialism. The need to balance market efficiency and social stability has left administrators considerable discretion, which has resulted in legal and practical uncertainty as regards the roles of government vs. markets⁴⁵.

In China, the statutes and institutions involved in food and medicine law are rather similar to the European ones. Superficially, the Chinese legal system thus seems similar to ours; however, China is still heavily influenced by tradition. The most important trace of Chinese history is in the close connection between strong central government (previously headed by the Emperor) and the administration⁴⁶. Historically, *the Emperor had all the power*. Each dynasty had its own legal code. There could be *no discussion on separation of powers*: local officials carried out all governmental functions at the bottom level⁴⁷. Separation between legislation, its execution, and adjudication is still unfamiliar to the Chinese.

Turning from the legal orders to business reality, European and Chinese food markets and food consumption patterns still differ greatly. This means the forms of business action regulated by food law differ in the EU as opposed to China. China faces the dual problem of malnutrition and over-eating. Use of milk and dairy products has been almost non-existent but is currently growing in China. The Europeans consume twice as much meat and fruit as the Chinese. In contrast, the Chinese consume twice as many vegetables. Only fish and seafood consumption figures are similar in the EU-15 and China.⁴⁸ With regard to medicines, consumption of Western medicines is growing faster than consumption in general in China⁴⁹.

In China, functional foods could be used to allow malnourished citizens to have an adequate daily nutrient intake. This potential side of functional foods is not at focus here. Instead we focus on nutritional problems that are common to Europe and China. In Europe, diet-related diseases are very common. Health is an important driver for food innovation⁵⁰, and the European market for functional foods is growing. Likewise, the Chinese market for functional foods is growing fast⁵¹ and in China the nutrition-related diseases are becoming more common, and consumers are acquiring affluence.⁵²

European and Chinese legislators are dealing with functional foods in their own ways. Chinese legal solutions concerning functional foods should be interesting to Western lawmakers

⁴³ Liu 2000.

⁴⁴ Jones 2003, 8.

⁴⁵ Peerenboom 2008 a, 3.

⁴⁶ Jones 2003, 8-9. This system of government developed over 2000 years ago and remained similar until the 20th century.

⁴⁷ Jones 2000, 9.

⁴⁸ Data and Trends of the European Food and Drink Industry 2006. CIAA report. Figures are from 2003.

⁴⁹ Li & Fung 2003.

⁵⁰ Data and Trends of the European Food and Drink Industry 2006. CIAA report.

⁵¹ Yeaman 2002.

⁵² The ratio of health products in the total expenditure of Chinese consumers is currently reaching that of Japanese or Western consumers China Health Products Association according to Functional Ingredients March 2005, China News.

because of thousands of years of Chinese tradition in treating diseases with nutrition⁵³. Knowledge of Chinese legislation is also important for Western companies, because the market potential in China is great due to the size of the market⁵⁴. Conversely, European legal solutions might be interesting for the Chinese. Currently, the EU is the largest food exporter in the world while China is fourth after the U.S. and Brazil⁵⁵. However, the EU's share of exports is shrinking in favour of Brazil and China.⁵⁶

Simultaneously to product markets, the European and Chinese legal systems are becoming analogous. For the past 30 years, the Chinese have put focus on “socialist justice” and legality. A lot of legislative work has been done, particularly economic reforms including modern legislation.⁵⁷ That is why differences between European and Chinese legislation are no longer considerable, at least superficially. A comparative research approach should be neutral in a sense that it does not presume one legal order superior to others⁵⁸. We try to avoid seeing European legal order as the inevitable endpoint for China, and look at both legal orders neutrally through a critical lens.

Donald C. Clarke has described methods for comparing Chinese law to Western, particularly American law. First, the naive ignorance approach, which needs to be avoided, views the two legal systems as similar and looks only at legal texts. We could also compare Chinese reality to “Ideal Western Legal Order”.⁵⁹ An alternative would be to see the “errors” as normal features of the Chinese legal system⁶⁰. A “disciplinary model” might be fruitful in understanding the Chinese legal system as the model is based on the assumption of state as Emperor. According to Clarke, no single model for describing Chinese law is perfect, and different models might be suitable for different fields of law or the same field at different times⁶¹.

1.5 Consumer Protection vs. Food Law and Medical Law

In this study, we discuss regulation of foodstuffs and medicines regarding the relationship between sellers and buyers. Guaranteeing safety and efficacy are responsibilities of the seller, and typical issues of consumer protection.⁶² We could thus say this study discusses consumer

⁵³ In the Chinese culture, it is deemed better to avoid illness by eating the right food at the right time, than curing it with medicine. There are even ‘medicinal restaurants’ in China, where one can order food on the basis of one’s ailments. Giract China news March 2006.

⁵⁴ China has a huge emerging middle class with high discretionary spending power. The middle class comprises of around 125 million people in 2005, and over 300 million by 2010. Doering 2005, 20. According to Doering, one of the main sectors that can benefit from the explosion of consumer demand is processed foods.

⁵⁵ China is followed by Canada, Australia, Thailand, Argentina, New Zealand, and Malaysia.

⁵⁶ CIAA: Data and Trends of the European Food and Drink Industry 2006.

⁵⁷ Huotari – Seppälä 2005, 132-133.

⁵⁸ Pöyhönen 1997, 247.

⁵⁹ A sophisticated researcher with this approach will notice features of the Chinese legal system that do not fit the Western model, but still see them as errors. If we try to understand Chinese law and where it is going, we cannot simply presume it is going towards Ideal Western Legal Order. Clarke 2003, 99-100.

⁶⁰ Clarke 2003, 100.

⁶¹ Clarke 2003, 102.

⁶² For example Leonard 2005 discusses food and medicine regulations under European consumer law, acknowledging both the health and safety aspect and economic interest aspect. Pages 227-229.

protection. The two viewpoints of consumer protection are the seller's perspective and the legislator's perspective.

However, regulation of foodstuffs and regulation of medicines are wider concepts than what is included in consumer protection. Safety and accurate marketing (in the case of functional foods: efficacy) of foods is only one of *food law* areas. Similarly, safety and efficacy of medicines is only one of *medical law* tasks.

According to Zhang, the concept of *food security* encompasses:

- adequacy of food supply or availability;
- stability of supply, without fluctuations from year to year or from season to season;
- accessibility of food or affordability; and
- quality and safety of food.⁶³

First, there must *be food* before the regulation of its qualities has relevance. Food security is “the right to food”, and is thus *a human rights issue*⁶⁴. Second, because food is one of the main commodities of international trade⁶⁵, food is *a trade issue*. This viewpoint relates to agricultural policies including subsidies, customs policies, and creating free trade areas. Harmonising consumer laws can be seen as one part of this international trade law regime. Third, as food production has wide consequences to the environment, food is also an *environmental issue*. At times food law is in fact classified under environmental law, as it is in Finland. ‘Food law’ is a concept that could be used to cover all of the above-mentioned legal perspectives on the agri-food business. As previously stated, we only deal with the consumer protection portion of food law.

Medical law is a rather young discipline and academic topic, but is gaining more interest. For example the Uppsala University in Sweden introduced a chair in this discipline in 2003. Their definition of medical law is the following: “Medical law deals with legal aspects of emerging scientific developments, concerning for example stem cell research, genetic diagnosis, reproduction technology or new e-health applications. Studies in this area of law can also include the regulation of pharmaceuticals and forensic medicine, as well as the organisation and supervision of health care and research, obligations and liability, the status and rights of patients and research subjects, etcetera.” Medical law “transcends traditional divisions, since it involves a number of legal areas such as public law, private law, criminal law and international law, as well as the relationship between law and ethics”.⁶⁶ As stated above, here we only deal with the consumer-protection -part of medical law.

1.6 Purpose of this Study: the Research Questions

From a typical lawyer's viewpoint, food and medicine law is unremarkable. For example, Jääskinen sees constitutional law, civil law, general administrative law, criminal law, and procedural law as legal system core. This leaves business law, such as the regulation of

⁶³ Zhang 2004, 566.

⁶⁴ Zhang 2004, 567.

⁶⁵ Zhang 2004, 567.

⁶⁶ Uppsala Universitet. Centre for Research Ethics and Bioethics.

foodstuffs and medicines, as *periphery*. Jääskinen compares laws on pig slaughtering vs. extradition of citizens, and sees them as “different things”.⁶⁷ By Tuori’s theory, we could also see principles of civil law, criminal law, etc. as part of the legal culture, and business law as a more labile surface-level phenomenon affected by changing market situations.

We see the “legal system core” as an area of law where lawyers have less competition from other sciences. Lawyers see that part of the legal system as more personalised. As business law is typically affected by economic considerations, and food and medicine law additionally by natural science, it is not seen as much as “law”. This means that even though periphery might be important in practice, it is less interesting for lawyers. According to Jääskinen, resistance to change is smaller in normative periphery that is outside “general” law⁶⁸. In other words, “real” law is more profound and stable than setting “technical” requirements on consumer goods that happen to be on the market this century. Historical perspective thus affects what is considered valuable legal research. We see this research as less traditional in this sense.

The aim of this thesis is, from *business law perspective*, to evaluate the somewhat complicated field of law that lies between food law and medicine law in the EU and China. We will focus on the law that typically affects functional foods as defined above, but will also discuss other relevant legislation. The reasons for the *comparative approach* were already discussed above. Primarily, businesses need to know of different rules that apply in different market areas. In addition, regulators might have something to learn from one another.

Foundations of food law and medicine law are discussed in chapter 2. This means mapping out the global framework and principles behind European and Chinese rules, and explaining how regulation on foodstuffs and medicines is drafted and implemented. In chapter 3, the borderline between the two categories of foodstuffs and medicines is discussed, focusing particularly on the question of how functional foods fit into these categories. Safety of foodstuffs vs. medicines is the topic of chapter 4, and efficacy and marketing of foodstuffs vs. medicines is the topic of chapter 5.

In chapters 6 and 7, the aforementioned legal issues will be summarised and conclusions will be drawn. This will be done separately from the entrepreneur’s perspective (chapter 6) and regulator’s perspective (chapter 7). ‘Entrepreneur’ here refers to a developer of functional foods, which refers to a certain type of product defined above.

From the *entrepreneur’s position*, the main legal questions to be answered are:

- 1) What are the rules affecting my business?
- 2) Where is the line between foodstuffs and medicines?
- 3) How safe must my product be? What is the procedure to prove safety?
- 4) How can I market my product? What is the procedure to prove efficacy?

An integral part of this viewpoint is a case study, included in chapter 6. *Three Chinese berries* (hawthorn fruit, emblic leafflower fruit, and barbary wolfberry) have been selected as test cases on how functional food legislation works. The three berries or their fractions could be used as raw material in different types of functional food products. The aim of the case study is to make the legislation more concrete and to find out *how product development faces regulation in practice*.

⁶⁷ Jääskinen 2008, 43.

⁶⁸ Jääskinen 2008, 43.

The berries were chosen as objects of research in the above-mentioned project between the universities of Turku and Beijing, because the berries have scientifically proven beneficial effects on metabolic syndrome⁶⁹. Metabolic syndrome is a suitable test case, as it is a globally common medical condition, and treating it is expensive. The berries are suitable test cases also because they are legally evaluated very differently due to differences in their traditional uses.

From a *regulator's perspective*, the main legal questions to be answered are:

- 1) Whether and where to draw the line between foodstuffs and medicines?
- 2) How to define safety requirements for foodstuffs vs. medicines?
- 3) How to regulate efficacy and marketing of foodstuffs vs. medicines?
- 4) When implementing safety and efficacy requirements, whether to rely on pre-market or post-market control?
- 5) Whether to resolve the above-mentioned legal issues locally (EU member state, Chinese province or city) or centrally (European Union, the People's Republic of China)?
- 6) Whether to resolve the above-mentioned legal issues by binding or non-binding instruments (hard law or soft law)?

The ultimate aims of regulating functional foods are presumably consumer protection and health promotion. This is also the goal of legislation on functional foods as defined above. Our presumption is that legislation is needed to promote research and development of new raw materials and products, to ensure the consumer's right to buy safe and effective products and to make informed decisions, and possibly to financially support healthy choices. Here we need to discuss whether food law, medicine law, and functional food law in particular are fulfilling their goals, and put functional food legislation into its societal context.

1.7 Materials for this Study

The basic materials for this study are the statutes and soft law documents on foodstuffs and medicines, including their preparatory and explanatory materials. A literature study has been made on European and Chinese food law and medicine law. The literature concerns legal rules on safety, efficacy and marketing of different types of health-related consumer products. Focus is on legal rules on functional foods. The literature used is mainly European, Chinese, and American.

European Community legislation has been viewed at EU web pages www.europa.eu, and national law on national legal web pages. With European laws, the official legal texts have been used. With Chinese legislation, we have had to rely on translations into English. Official translations are not available. The translations used are by various translators: Chinese ministries, ChinaLawWeb by the University of Maryland, United States Department of Agriculture Foreign Agricultural Service, law firms situated in Europe, China or the United States, or by Miao Qing at University of Turku. For some laws, there have been several translations available. In these cases, selection of translation was based on perceived expertise of the translator.

⁶⁹ Encompassing obesity, type 2 diabetes, and cardiovascular disease.

The local laws of EU Member States and Chinese provinces and cities are not studied in detail. Local rules or procedures are mentioned or discussed when they are considered particularly important in legally evaluating functional foods, as is the case with the European food vs. medicine issue. The general trend in both Europe and China is towards harmonisation. This means European food and medicine laws are often given at Community level, and Chinese laws at national level⁷⁰.

As we have focused on legislation, discussion on administrative practice and court cases is limited in this study. We see food and medicine law as constant negotiation between authorities and entrepreneurs, where the role of courts is typically not important. Administrative guidelines as soft law will be discussed in connection with hard law. Instead of cases, we use these guidelines as proof on how legislation is implemented and interpreted in practice. This is a deficiency, particularly with regard to China, where the role of administrative practice is important, and would deserve further study.

⁷⁰ The question of central vs. local legislation will be discussed below.



2 LEGAL FOUNDATIONS

In this chapter, we discuss the very basic foundations of European and Chinese law on foodstuffs and medicines⁷¹ by mapping out the global background, the legal institutions involved, and the sources of law. The question of ‘hard law’ vs. ‘soft law’ is integral here. Drafting the law and implementing the law cannot always be distinguished, as the regulatory agencies have their role in both.

2.1 Global Background

Before we turn to EU and Chinese law, we will briefly discuss the global harmonisation of food and medicine laws, as it creates the framework in which the EU and China operate.

2.1.1 WTO Agreements

The World Trade Organization was established in 1994 after the Uruguay round of GATT negotiations. The WTO consists of negotiations, agreements, and dispute resolution. The most important agreements from our perspective are the Technical Barriers to Trade Agreement (TBT Agreement) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). The TBT Agreement covers all *mandatory and voluntary* technical regulations and standards, including testing and certification procedures. The aim of the agreement is that these technical measures do not create unnecessary obstacles to trade.⁷² The SPS Agreement defines the rights and obligations of members with respect to application of sanitary and phytosanitary measures meaning laws and standards on food safety, animal health and plant health. Basically, the SPS agreement defines how food is to be regulated in order to maintain TBT agreement goals⁷³.

⁷¹ From consumer protection perspective as described above.

⁷² Wanhua 2002, 316.

⁷³ Hollo 2008, 26.

The GATT agreement established the fundamental principles of international trade: the *most-favoured-nation treatment*⁷⁴, and *national treatment*.⁷⁵ Most-favoured-nation treatment means that if a Member grants an advantage to a product from another country, the same advantage shall be granted to similar products of all other Members. Likewise, restrictive practices must be applied in a universal fashion⁷⁶. National treatment means that Members apply equal taxation and regulation to imports compared to domestically produced or supplied goods.⁷⁷ The GATT agreement was incorporated into the WTO. The principles of non-discrimination are also included in GATS (services) and TRIPs (intellectual property rights) agreements, the TBT agreement⁷⁸, and the SPS agreement⁷⁹.

In law, there are always exceptions to rules. Wilkinson distinguishes *eight instances* in the GATT agreement which allow Members to engage in discriminatory practices against each other. For example, free trade areas among certain members are allowed, new Members can be discriminated against, and infant industries can be protected⁸⁰. The most interesting exception category is the ‘general exceptions’ that include a wide range of criteria including “the protection of human, animal or plant life or health”. The GATT, the TBT, and the SPS Agreement allow Members to adopt exceptions on these grounds⁸¹. This means a country may, for example, prohibit imports of foods from a certain Member country. According to the TBT Agreement, risks must be assessed based on available scientific and technical information⁸². Sanitary and phytosanitary measures have to be based on scientific evidence⁸³. Measures shall not constitute arbitrary or unjustifiable discrimination or disguised restrictions on international trade⁸⁴.

China joined the WTO in 2001⁸⁵. China is expected to comply with the WTO agreements and develop into a “more responsible member of the international community”⁸⁶. Foreign businesses expected to benefit from a more transparent and predictable business environment⁸⁷. The worst possible scenario was that China would disrupt the whole WTO process that is

⁷⁴ “Any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.” GATT 1994, Article I, paragraph 1.

⁷⁵ “The products of the territory of any contracting party imported into the territory of any other contracting party shall not be subject, directly or indirectly, to internal taxes or other internal charges of any kind in excess of those applied, directly or indirectly, to like domestic products.” GATT 1994, Article III, paragraph 2.

⁷⁶ “The exports of a Member must not be prohibited or encounter restriction into domestic markets, unless the importation of the like product of all third countries is similarly prohibited or restricted.” GATT 1994, Article XIII, paragraph 1.

⁷⁷ Wilkinson 2000, 81-82.

⁷⁸ Article 2 paragraph 1.

⁷⁹ Article 2 paragraph 3.

⁸⁰ In addition, the WTO does not say anything about discriminating against non-Members. Wilkinson 2000, 85.

⁸¹ GATT Article XX, TBT Article 2 paragraph 2, SPS Article 2. Other grounds for these safeguard measures include ensuring the quality of the country’s exports, protection of environment and prevention of deceptive practices. Wanhua 2002, 316.

⁸² Article 2 paragraph 2.

⁸³ Article 2 paragraph 2.

⁸⁴ TBT preamble, SPS Agreement Article 2 paragraph 3.

⁸⁵ This happened after lengthy discussions with the most important trading partners. As a non-member, China’s exports were often the subject of discriminatory treatment in overseas markets. By adjoining, China gained new market access opportunities and new legal protections against discrimination. Gong 2005.

⁸⁶ Kobayashi 2008, 1.

⁸⁷ Qingjiang 2002, v.

based on consensus⁸⁸. According to US-China Business Council in 2008, China has gone a long way in fulfilling its WTO obligations, but there are still problems related to the principle of national treatment in particular. This means that foreign companies experience adverse treatment compared to Chinese companies. Discrimination comes in the form of stricter regulations and enforcement, more stringent, time consuming, or costly application and licence approval processes, exclusion from the standards setting process, and bias towards domestic goods in government procurement.⁸⁹ According to Peerenboom, some of the areas listed by foreign investors are actually required of China by the WTO, while others are just wishful thinking seeking to further foreign interests⁹⁰. Besides factors related to the Chinese legal culture, employment and income levels of the Chinese people will determine whether China will fulfil its WTO obligations⁹¹.

Disputes arise when trade restrictions are justified by somewhat ambiguous goals such as human health. The most famous food disputes resolved by the WTO Dispute Settlement Body are the ‘hormones in beef case’⁹² of 1998 and the ‘sardine case’⁹³ of 2002. The EC banning beef hormones was not justified according to the SPS agreement, nor was the EC restriction of the use of the term ‘sardine’ justified according to the TBT agreement, because neither was based on Codex. Here we see the connection between Codex standards and WTO disputes. With regard to China, absence of disputes against China is seen as a sign of China’s reasonably effective implementation of the WTO rules⁹⁴. Lack of disputes could also be a sign of lack of confidence on the WTO system. Jackson is of the view that WTO members do trust the dispute settlement procedures, and sees dispute resolution as the heart of the WTO⁹⁵.

If WTO law is breached, the primary obligation is to bring the unlawful measure into conformity with WTO law. If a state does not implement the ruling of the Dispute Settlement Body, the WTO agreements provide for remedies: compensation or countermeasures. Both are temporary, emphasising that the primary obligation is to remove the unlawfulness. Compensation is preferred to countermeasures, but as compensation must be agreed between the parties of the dispute, countermeasures are often the only alternative in practice.⁹⁶

Trade sanctions, which proved to be inefficient against large trade powers⁹⁷, are anticipated to be inadequate against China. The WTO mechanisms generally resolve whether certain national legislation contravenes WTO agreements. The WTO does not resolve issues such as hierarchy of norms, competences of authorities, resources for implementation, or enforcement of judgments.⁹⁸ These general legal issues remain the important factors of legal risk management that foreign businesses must face in China.

⁸⁸ Qingjian 2002, vi.

⁸⁹ US-China Business Council 2008, 10.

⁹⁰ Peerenboom 2008 b, 8.

⁹¹ Qingjiang 2002, 308.

⁹² EC measures concerning meat and meat products (*Hormones*), WT/DS48/AB/R of 16 January 1998. (AB-1997-4).

⁹³ WT/DS231/R of 29 May 2002.

⁹⁴ Mertha 2008, 1.

⁹⁵ Jackson 1998, 59.

⁹⁶ Nordblad 2003, 88.

⁹⁷ See Lindblad analysis of the *Bananas* case and the *Hormones* case, Lindblad 2003, 99.

⁹⁸ Seppänen 2005, 587.

The EC and China are simultaneously recipients and makers of international standards. There are several parties involved in making these standards, the United States among them. This makes international food law a constant negotiation and a series of compromises. Every state pursues individual ideas on how the law should be developed. Lately Codex Alimentarius Commission has paid more attention to horizontal standards applicable to all foods. Emphasis has been placed on principles of scientific risk assessment, the precautionary principle, traceability, and views from consumers and NGOs. Besides plain natural science, *other legitimate factors* are considered, such as economics and characteristics of different regions and countries.⁹⁹

The precautionary principle and the need to consider factors other than science in determining food standards are something the EU has demanded, and the United States have resisted¹⁰⁰. The EU earlier argued in the above-mentioned EU – Hormones case that *the precautionary principle* is a customary rule of international law or at least a general principle of international law. The EU had prohibited import of beef hormones. According to the precautionary principle, WTO member states are allowed to take precautionary measures in the absence of full scientific certainty. According to Wanhua, the EU lost the hormone case because the precautionary principle was still considered to await authoritative formulation.¹⁰¹ The Cartagena Protocol on Biosafety entered into force in 2003, and clearly embraces the precautionary principle. The Cartagena Protocol refers to the Rio Declaration on Environment and Development 1992 in this issue, and the Rio Declaration was already written in 1992. It seems that those in favour of the precautionary principle see it emerging in the 1990s at the latest, and those against it still resist its existence.

The role of the WTO in building international legal principles is under discussion. The WTO can either focus on resolving disputes in a bilateral and practical case-to-case approach, or it can build international rule of law. Consistency and abiding by the rules is integral for the credibility of the Dispute Settlement Body¹⁰². Nordblad is of the view that the WTO needs stronger remedies to be able to achieve rule-oriented dispute settlement. He is also of the view that effective remedies are those that repair damage *and* induce compliance, and thus compensation and countermeasures are both needed. Compensation and countermeasures should be considered separate issues. Rule integrity would be enhanced by the situation where countermeasures were free of the compensatory element.¹⁰³

2.1.2 Global Standards

2.1.2.1 ISO Standards

The TBT Agreement requires that technical regulations and international standards are developed and implemented in a non-discriminatory manner, and without creating unnecessary

⁹⁹ Kan – Zhang 2002.

¹⁰⁰ Poli 2004, 614. The European Community applied for full membership of Codex so that it could better pursue its goals, which often clash with US goals.

¹⁰¹ Wanhua 2002.

¹⁰² See Palmujoki 2003, 719, as regards the role of the WTO dispute resolution body in evaluating the acceptability of national environmental legislation.

¹⁰³ Nordblad 2003, 103.

obstacles to trade. The TBT Agreement also recommends the recourse to international standards wherever possible while drafting technical regulations.¹⁰⁴ ISO/IEC¹⁰⁵ standards are particularly referred to in the TBT Agreement¹⁰⁶. ISO is the International Organisation for Standardisation, and has published several standards related to the food industry. For example the International Standard ISO 22000:2005 is promoted in the following manner: “food safety management system meeting the requirements of the Standard could be the entry ticket to increased business in the global market and participation in cross-border food supply chains”^{107, 108}.

ISO is a non-governmental organisation “forming a bridge between the public and private sectors”, and a network of the national standards institutes of its 157 member countries. Many of the member institutes are part of the governmental structure of their countries, while others have been set up by national partnerships of industry associations.¹⁰⁹ Legally describing ISO standards is difficult. They are not agreements between states as Codex standards, and they are not self-regulating because governments are involved. They are followed voluntarily, although abiding by a standard might be required in practice. In any case, ISO standards can be defined as *soft law*.

The EU sees international standards as a positive phenomenon. According to the European Commission, it will, in co-operation with the European Standards Organisations, “continue to encourage the development of international standards and promote their use”. International standards shall be transposed into European standards and European law, “wherever possible”. And vice versa, the EU is willing to diffuse European standards internationally, particularly to neighbouring countries.¹¹⁰ The lead in developing globally accepted standards is seen as a lead to markets.

2.1.2.2 Food Standards: Codex

Codex Alimentarius is an international organisation governing foodstuffs and operating under United Nations organisations FAO¹¹¹ and WHO¹¹². Codex documents are global food law¹¹³. Codex Alimentarius pursues to protect the health of consumers and to promote fair international food trade.¹¹⁴ Codex Alimentarius Commission is the highest decision-making body, where the

¹⁰⁴ Commission Communication on Standards 2004, 7.

¹⁰⁵ “The International Electrotechnical Commission is the international standards and conformity assessment body for all fields of electrotechnology.” <http://www.iec.ch/>.

¹⁰⁶ Annex 1 of the Agreement.

¹⁰⁷ ISO web page. http://www.iso.org/iso/publications_and_e-products/checklists.htm.

¹⁰⁸ ISO 22000 is the standard on food safety management systems, including requirements for any operator in the food chain. Other important standards related to the food industry are: ISO/TS 22003:2007, which includes requirements for bodies that provide audits and certification of food safety management systems, ISO 22005:2007, which is about traceability in the feed and food chain, and ISO 24276:2006, which standardises methods of analysis for detecting GMOs. ISO web page. http://www.iso.org/iso/catalogue_detail?csnumber=35466.

¹⁰⁹ ISO web page. <http://www.iso.org/iso/about.htm>.

¹¹⁰ Commission Communication on Standards 2004, 3-4.

¹¹¹ Food and Agriculture Organization.

¹¹² World Health Organization.

¹¹³ Codex Alimentarius means food law.

¹¹⁴ www.codexalimentarius.net.

representatives of the approximately 180¹¹⁵ member states meet. The Commission assembles every year. The Codex Alimentarius Commission is the most important global actor drafting food standards. The European Community, represented by the Commission¹¹⁶, EU Member States separately, and China are members of Codex.

Codex documents are in the forms of standards, codes of practice, guidelines, principles, recommendations, etc. Standards often relate to product features and can be very precise setting for example MRLs (maximum residue levels) for pesticides or medicinal substances in foods. For example there is a standard for canned baby food and a standard for frozen spinach. Codes of practice guide procedure concerning production, preparation, transport and storage, including HACCP systems. Guidelines exist on nutrition and health claims¹¹⁷ whereas principles are more general and relate to import and export certificates. The division between different document types is not important as none of the Codex documents are directly binding on food industry operators. All of the above-mentioned document types are listed under 'standards' on the Codex web page¹¹⁸.

What makes Codex rules more important is the fact that they are specifically referred to in two WTO¹¹⁹ agreements: the Technical Barriers to Trade Agreement (TBT Agreement¹²⁰) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement¹²¹). This means *Codex standards are used as a reference in trade disputes at the WTO*.¹²² It is important for the EC and China to defend their interests in Codex, as they are also members of the WTO¹²³. The role of the Codex Commission is to provide a political forum to debate issues. The role of the WTO Dispute Settlement Body is to ultimately resolve the issues that cannot be agreed upon.

2.1.2.3 Medicine Standards

The above-mentioned WTO agreement on Technical Barriers to Trade (the TBT agreement) applies also to medicines. For example, in the November 2007 meeting of the Technical Barriers to Trade Committee, Columbia raised a concern on Argentina's regulations for

¹¹⁵ Counted on Codex web page http://www.codexalimentarius.net/web/members_area.jsp?lang=EN, April 2007.

¹¹⁶ More precisely its Directorate General on Health and Consumer Protection.

¹¹⁷ CAC/GL 23. 1997. Revised 2004, amended 2008.

¹¹⁸ http://www.codexalimentarius.net/web/standard_list.do?lang=en.

¹¹⁹ World Trade Organization.

¹²⁰ The TBT Agreement covers all *mandatory and voluntary* technical regulations and standards, including testing and certification procedures. The aim of the agreement is that these technical measures do not create unnecessary obstacles to trade. Wanhua 2002, 316.

¹²¹ The SPS Agreement defines the rights and obligations of members with respect to application of sanitary and phytosanitary measures. This means laws and standards on food safety, animal health and plant health.

¹²² World Health Organisation web page. Biotech: 20 questions. <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

¹²³ The EC Member States including Finland have been WTO members since its inception in January 1995, and China since December 2001. WTO has 150 members as at June 2009.

pharmaceuticals. These regulations involve, for example, application of tariffs or fees for undertaking verification visits to plants located in the countries of origin¹²⁴.

The WHO is involved in developing international medicinal products law. They develop international norms, standards and guidelines, and provide guidance, technical assistance and training to support countries in adopting these standards on medicinal products.¹²⁵ The WHO also organises international conferences of drug regulatory authorities, where medicinal products law is discussed. The outcome of these meetings is “Recommendations”, in which various areas of medicinal products laws are discussed. They take the form “Member States should...”. In 2006, it was agreed that member states should support clinical studies of herbal medicines¹²⁶, and seek efficient sanctions for false drug advertising, particularly internet advertising¹²⁷. According to European law, the European Medicines Agency (EMA) shall “participate actively in international scientific dialogue and to contribute to international scientific harmonisation and technical cooperation with the WHO”¹²⁸. China is also involved in the WHO discussions and drafting recommendations on medicinal products law.

The ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) is a project for global harmonisation of the medicine authorisation procedures. Its Steering Committee selects the topics for international harmonisation. However, the ICH is not global: it brings together the regulatory authorities of Europe, Japan and the United States, in addition to experts from these three regions¹²⁹. In the EU, draft ICH guidelines are subject to EU-wide public consultation. Once adopted by the CHMP¹³⁰ of the EMA, the *ICH guidelines have the same status as other European scientific guidelines* and replace existing guidelines on the subjects covered. ICH guidelines may also be developed on subjects that do not come within the scope of scientific guidelines.¹³¹

The EU and China also work bilaterally on issues of medicine law. The agreement on “Consultation and Cooperation Mechanism” was signed in 2008. In 2009, the Chinese SFDA met with DG Enterprise of the EC in the first annual high-level working conference under the “mechanism”. According to the SFDA, the conference announced the achievements of the medicine and medical device workgroups, and discussed establishment of a workgroup on cosmetics. In addition, the EMA was present.¹³²

¹²⁴ World Trade Organization. Committee on Technical Barriers to Trade. Specific Trade Concerns Relating to Access of Pharmaceuticals to the Argentine Market. Communication from Colombia. G/TBT/W/280. 30 October 2007.

¹²⁵ WHO web page. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/en/index.html.

¹²⁶ Icdra. 12th International Conference of Drug Regulatory Authorities. Recommendations. Page 5.

¹²⁷ Icdra. 12th International Conference of Drug Regulatory Authorities. Recommendations. Page 8.

¹²⁸ Regulation 726/2004/EC, preamble 27.

¹²⁹ ICH web page : <http://www.ich.org>.

¹³⁰ The Committee for Human Medicinal Products.

¹³¹ Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMA/P/24143/2004. Page 8.

¹³² SFDA web page at: <http://former.sfda.gov.cn/cmsweb/webportal/W43879541/A64029996.html>.

2.2 EU Law on Foodstuffs and Medicines

2.2.1 Hard law¹³³

European law on foodstuffs and medicines is a puzzle consisting of EU laws and Member State Laws. Both consist of hard law (binding) and soft law (non-binding) instruments. European Union law is prepared by the European Commission. Food safety is under the competence of Directorate General on Health and Consumer Protection (DG SANCO)¹³⁴. DG SANCO is responsible for public health, general consumer protection, and food safety in particular. Medicine law is drafted by the Commission's Directorate General for Enterprise & Industry (DG Enterprise)¹³⁵. The main goal of DG Enterprise is to ensure competitiveness of European enterprises and facilitate job creation and economic growth¹³⁶.

The EU Member States also have their own food and medicine laws. The EU has 27 Member States as of 2007. The division of work between EU level and member state level legislators is the basic question in EU law. According to Nedergaard, European cooperation clearly has federalist as well as intergovernmental traits. The mixed traits reflect the basic contrast in the EU between the desire for some degree of supranational governance and the Member States' perceived need for control.¹³⁷ The EU cannot operate without competences, which are outlined in the articles in the EC Treaty. If a question does not belong to EU competence, then Member States have the authority to decide upon it.

The competence of the Commission to act in the area of food law can be based on Treaty Articles 37, 95, 152 and 153. Sometimes food law is based on more than one Article, such as Article 95 on creating the internal market, and Article 152 on safeguarding public health. Article 37 concerns agriculture and Article 153 consumer protection. The central legislation on medicines from consumer perspective¹³⁸ is based on Articles 95 and 152. Apparently, food and medicine laws are not seen primarily as consumer issues but rather as issues of free trade and public health.

Certain questions fall under the exclusive competence of the Community. On food and medicine issues, both the EU and the Member States have the competence to enact legislation. In this case, the principle of subsidiarity applies, meaning the EU shall take action only when it is more effective than action taken at national, regional or local levels¹³⁹. In case of contradiction, the *principle of primacy* applies: EU law is to be enforced instead of contradictory national law.¹⁴⁰ Another important principle is *the principle of proportionality*: the EU involvement must be limited to what is necessary to achieve the objectives of the

¹³³ Hard law here means regulations that are enforceable by courts.

¹³⁴ The Commissioner in charge of DG SANCO at the moment (2009) is Androulla Vassiliou.

¹³⁵ The Commissioner at the moment (2009) is Günter Verheugen.

¹³⁶ European Commission web page. http://ec.europa.eu/enterprise/dgs/index_en.htm.

¹³⁷ Nedergaard 2007, 7.

¹³⁸ Directive 2001/83/EC and Regulation 726/2004/EC.

¹³⁹ European Union web page. http://europa.eu/scadplus/glossary/subsidiarity_en.htm.

¹⁴⁰ Tolonen 2003, 111-112.

Treaties^{141, 142} The proportionality principle also applies to actions of Member States, and has been used particularly with regard to limiting the four freedoms¹⁴³.

Food safety is considered very important particularly from free trade and public health perspectives. This leads to the conclusion that EU legislation is usually considered necessary and to a situation where the amount of EU legislation is vast. At the moment, EU food law covers all the important aspects and functions in the food chain: biological safety (hygiene), chemical safety (contaminants, residues, additives etc.) and practically all aspects of food marketing. For example in the 2008 novel food proposal, it is stated that Member State action could lead to differing levels of food safety, confuse consumers, and endanger the free movement of food in the EU¹⁴⁴. In the 2008 labelling proposal, it is stated that Community action is needed “for the internal market to function smoothly”¹⁴⁵. The EU has regulated medicines since 1965, and the role of national regulators has been rather small for a long time.

EU law can be divided in primary legislation, secondary legislation, international agreements, legal principles, and case law. Primary legislation means the Treaties, which are comparable to constitutional law. The two fundamental treaties are the Treaty establishing the European Community (EC Treaty) and the Treaty establishing the European Union (EU treaty). In this study, we are mainly interested in secondary legislation. Secondary legislation means Regulations, Directives, and soft law materials such as Recommendations or Opinions. Regulations are directly applicable and binding on everyone, whereas Directives are binding on the Member States.¹⁴⁶

When choosing a legal instrument, Regulations are today often favoured compared to Directives. In the 2008 labelling proposal, it states “a Directive would have lead to an inconsistent approach in the Community leading to uncertainty for both consumers and the industry”. A Regulation provides “a consistent approach for industry to follow and reduces the administrative burden as they do not need to familiarise themselves with the individual Regulations in the Member States”.¹⁴⁷ With novel foods, the Directive option was not even considered in 2008, because there is already a novel food Regulation and the evaluation has, since 1997, been based on EU-wide approvals. Instead, the Commission stated why soft law is not considered adequate for addressing the issue in question: “Non-legislative action based, for example, on a code of good practice or guidelines could not give sufficient protection and would lack legal certainty.”¹⁴⁸

Minimum harmonisation means that the EU sets ground which national legislation must meet. Legally, this is often done by a Directive, which includes a safeguard clause. In this case, EU Member States may enact more restrictive laws if unexpected events such as public health

¹⁴¹ European Union web page. http://europa.eu/scadplus/glossary/proportionality_en.htm.

¹⁴² Both the principle of subsidiarity and the principal of proportionality are established by Article 5 of the Treaty establishing the European Community. Protocol (No 30) on the application of the principles of subsidiarity and proportionality was Annexed to the EC Treaty in 1997.

¹⁴³ Raitio 2006, 246. The four freedoms of the EU are: the free movement of persons, goods, services, and capital.

¹⁴⁴ The proposal for a Regulation on novel foods. Explanatory memorandum. Page 5.

¹⁴⁵ Food labelling proposal 2008. Explanatory memorandum. Page 9.

¹⁴⁶ European Union web page, EurLex, Process and players. http://eur-lex.europa.eu/en/droit_communaire/droit_communaire.htm#1.6.

¹⁴⁷ Food labelling proposal 2008. Explanatory memorandum. Page 11.

¹⁴⁸ The proposal for a Regulation on novel foods. Explanatory memorandum. Page 6.

reasons render the EU mandates too limiting. Of the general consumer protection laws, the *product safety directive* includes a safeguard clause. A problem with minimum harmonisation is that national rules can be used for protectionist purposes. According to the Commission's current Consumer Protection Strategy, minimum harmonisation is not a suitable alternative in consumer protection issues anymore as it leads to restrictions on free trade¹⁴⁹.

Maximum harmonisation means "full" harmonisation. The *unfair commercial practices directive* uses maximum harmonisation, and does not include a safeguard clause. Legislators in Member States cannot create rules that are more restrictive on trade than the Directive. However, national courts may create varying standards for acceptable commercial conduct on a case-by-case basis. Ultimately, the European Court of Justice may have to ensure harmonisation through case law, as it resolves disputes that challenge a Member State's trade practices laws.¹⁵⁰ This means that not even maximum-harmonisation directives as such can amount to full harmonisation. Rules would have to be very detailed in order to fully harmonise a subject area, and general clauses would have to be avoided. Full harmonisation is thus hypothetical as it would mean no room or need for courts, however, in practice, harmonisation will have to come through courts dealing with cases, and ultimately through the ECJ.

The Commission is of the view that consumer protection is better achieved by maximum harmonisation, but the foremost concern seems to be the removal of barriers to trade¹⁵¹. MacMaoláin has criticised EU food laws for allowing the principle of free movement of goods to underlie all harmonising provisions¹⁵². This means the profitability of the European food business is the Commission's foremost concern, at the expense of health and consumer protection. According to him, EU law has often become an artificially low regulatory "ceiling". He also argues that much of EU food law has developed in reaction to food safety crises and thus neglected quality aspects of food, such as nutritional value and ethical issues. MacMaoláin believes national-level regulators could be more responsive to citizen's public health and other concerns.

Above, we have discussed law that is harmonised in the EU either through maximum harmonisation or through minimum harmonisation. The actions of Member States would still be limited if law were not harmonised since free movement of goods in the EU is guaranteed by rules in the EC treaty. Customs duties are prohibited¹⁵³, and Member States are not allowed to quantitatively restrict import¹⁵⁴ or export¹⁵⁵ of goods. The ultimate quantitative restriction is a ban to import for example a food or a medicine. A member state can, however, restrict imports if it is necessary *for the protection of health and life of humans*.¹⁵⁶ The European Court

¹⁴⁹ EU Consumer Policy strategy 2007-2013. COM(2007) 99 final. Page 7.

¹⁵⁰ Nehf 2006.

¹⁵¹ EU Consumer Policy strategy 2007-2013. COM(2007) 99 final.

¹⁵² MacMaoláin 2007, 2.

¹⁵³ Article 25 of the Treaty.

¹⁵⁴ Article 28 of the Treaty.

¹⁵⁵ Article 29 of the Treaty.

¹⁵⁶ Article 30 of the Treaty is called the safeguard clause: "The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Member States."

of Justice has handled cases related to food and medicine law where it has decided whether certain Member State actions have or have not been necessary¹⁵⁷.

Different rules apply to *maintaining vs. introducing* derogations to harmonised rules. When legislation is harmonised according to Article 95 in order to achieve free movement of goods, a member state can still uphold certain existing national rules deemed necessary for Article 30 or other reasons¹⁵⁸. Setting up new national rules requires scientific evidence on particular problems occurring after or caused by European legislation¹⁵⁹.¹⁶⁰ The Commission must be notified of derogations, and if the Commission does not react, derogations are considered legal.

The principle of *mutual recognition* further clarifies the roles of the EU vs. its Member States when standards are not harmonised by EU level legislation. This principle was established by the *Cassis de Dijon* case already in 1979. It prevents a Member State from blocking a product at its borders if the product is approved according to another Member State's reasonable standards. Because food and medicine law is widely harmonised in the EU, the *Cassis* doctrine is not particularly relevant here.

2.2.2 Administrative Soft Law

So far, we have discussed the creation of European hard law norms. Now we turn to soft law, which is in the field of foodstuffs and medicines at the EU level created by the Commission and the regulatory agencies. Senden sees the European Commission as quite an aggressive maker of soft law, and warns that it may use recommendations, codes, etc. as a means to impose obligations, which are not in fact entailed in Community law¹⁶¹. To promote democratic legitimacy, she supports active participation of the European Parliament in the making of soft law¹⁶². The Council already consults the Parliament when making recommendations¹⁶³.

When turning to the agencies EFSA and EMEA, the democratic element is even thinner than with the Commission. Supranational regulatory agencies are an important institutional innovation in European law. These agencies have emerged since the 1990s, and are set up in sensitive policy areas. The agencies replace the traditional committee system as the main regulatory institution of the EU. The European Medicines Agency (EMA) was established in

¹⁵⁷ These cases from the 1970's and 1980's have involved for example certificates for medicines, food fortification, additives, and sausages. Joutsamo et al. 2000, 436-437.

¹⁵⁸ Article 95(4): "If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them."

¹⁵⁹ Article 95(5): "Moreover, ... if, after the adoption ... of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them."

¹⁶⁰ Hollo 2008, 38.

¹⁶¹ Senden 2004, 492.

¹⁶² Senden 2004, 482.

¹⁶³ Senden 2004, 502.

1993. The European Food Safety Authority (EFSA) was set up in 2002, following the example of medicines regulation.¹⁶⁴

According to Regulation 726/2004/EC, European medicine law should be based on science¹⁶⁵. The *European Medicines Agency (EMA)* is responsible for preparing scientific opinions on medicinal product legislation, providing the industry with regulatory and scientific guidelines, and handling applications in the centralised procedure. The opinions are prepared by the EMA Committees, which are: the Committee for Medicinal Products for Human Use (CHMP), the Committee on Orphan Medicinal Products (COMP), the Committee on Herbal Medicinal Products (HMPC), and the Committee on Paediatric Medicinal Products (PDCO).¹⁶⁶ According to Krapohl, the establishment of the EMA led to a successful regulation of pharmaceuticals in the EU. A real single market is emerging and the regulatory policymaking seems to function. The EU Member States and the industry evaluate the EMA very positively.¹⁶⁷

One goal of setting up the EMA was that scientific advice for future applicants seeking marketing authorisation would be generally provided and in greater depth¹⁶⁸. The EMA publishes its own guidelines on quality, safety and efficacy testing requirements; which is described as *giving scientific advice and protocol assistance*. The “advice” by the EMA, while understood as law, is not legally binding, so it is in reality soft law, and is in practice very important as it gives the regulation target the actual rules on how to act.

According to the General Food Regulation, food law should be based on scientific risk assessment, which is further defined by the precautionary principle. Scientific risk assessment is the task of the *European Food Safety Authority (EFSA)*, established in 2002. The EFSA gives scientific advice to the Commission when drafting new laws or making pre-market approvals. The EFSA also gives advice to national legislators and food agencies. Similar to the EMA, the EFSA also addresses regulation targets by their opinions and guidelines. They advise the applicants on how to draft applications and what information is needed, forming the hard law requirements into practical demands.

The reason for setting up the EFSA was to regain the public’s trust after scares related to BSE and dioxin. Before EFSA, a committee that was directly a part of the Commission handled scientific risk assessment in food issues. It had become obvious that the Member States and the Commission could not agree among themselves on food law issues based on science, and an impartial expert authority was seen as the answer. EFSA’s structure and their use of outside experts are meant to ensure that science and politics are distinguished.¹⁶⁹

¹⁶⁴ Krapohl 2004, 518.

¹⁶⁵ Preambles of the Regulation refer to “high level of scientific evaluation”, “objective scientific criteria of quality, safety and efficacy”, “scientific expertise”, and “scientific role and independence of the committees”.

¹⁶⁶ Regulation 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. The Committee on Pediatric Medicinal Products was established in 2007. There is also the fifth Committee for veterinary medicinal products, which are not discussed in this thesis.

¹⁶⁷ Krapohl 2004, 519.

¹⁶⁸ Regulation 726/2004/EC, preamble 25.

¹⁶⁹ ElAmin 2006.

The EU faces the task of balancing the interests and goals of 27 economically and culturally different Member States in regulating foods or medicines. The crucial issue for successful risk regulation is how Member State interests and scientific expertise can be integrated. The issue of science vs. politics applies both to medicines and foodstuffs. The Member States have long-term interests in appropriate risk regulation based on science, but they also have short-term interests to protect their domestic economy in single cases. Agencies like the EMEA and the EFSA were established so that the common long-term interests could prevail.¹⁷⁰

Expertise and independence are valuable assets in the current EU where all the Member States are perceived to pursue their own interests. Compared to democracy, in other words politics, the targets of regulation prefer a scientific community to resolve the issues. Separate regulatory agencies are preferred compared to the Commission and its committees, because the Commission is no model example of transparency.¹⁷¹ For example, with novel foods, most stakeholders want EFSA to resolve the issues of whether a food can be regarded as novel and whether a food can be authorised. National governments are also distrusted and seen as creating nothing but hurdles to trade, often on political grounds.

As a result of the control problem, the Member States have not given the Agencies total independency, though. The decision-making procedures still involve the Commission and Member-State bodies. In this situation, one has to be aware that the short-term interests of the Member States are blocked from being involved. As regards the European regulatory agencies of foodstuffs and medicines, the EFSA has been criticised for not being as independent as the EMEA.¹⁷² Member States of the EU have a larger role in the EFSA decision-making procedures than within EMEA procedures. This way politics and national interests influence European food law more than European medicines law.

According to Herman Koeter, the EFSA's deputy executive director, it is a challenging task for the EFSA to maintain their independence. The EFSA receives pressure from the European Parliament, the Commission, national legislators, regulatory agencies, and the food industry. There is a push to dilute or strengthen results, and sometimes push for a firm opinion in cases where science is unable to yield a clear answer. Risk communication is also a sensitive issue. The EFSA has decided to inform the public directly on key issues and scientific findings, in spite of the public sometimes misinterpreting science and turning away from a particular type of food.¹⁷³ Scandal-type media attention is naturally bound to damage a member state or an economic sector. Thus there is sometimes political pressure *against* basing food law on science.¹⁷⁴

While the EFSA has trouble in being independent enough, some critics have argued that both the EFSA and the EMEA are too independent, as they have no accountability to democratically elected agencies. Leino has questioned the legal grounds for EU agencies such as the EFSA and the EMEA, and according to her, the role of agencies should be clearly -and strictly- defined in law. She demands that all legislative acts and also decision-making affecting private rights and obligations should be made by politically accountable actors. Such powers should not be delegated to agencies,¹⁷⁵ and this is far from reality at the moment. With

¹⁷⁰ Krapohl 2004, 520.

¹⁷¹ Leino 2003, 48.

¹⁷² Krapohl 2004, 521.

¹⁷³ Koeter according to ElAmin 2006.

¹⁷⁴ The decision on EFSA location in Parma was itself clearly a political one.

¹⁷⁵ Leino 2003, 49-50.

foodstuffs and medicines, *EU level and national regulatory agencies have very important roles in both drafting the law and implementing the law*. Aside from giving advice for drafters of hard law, the agencies have created a vast amount of documents defined as soft law, which gives hard law its actual contents. The agencies also have significant discretionary powers in law implementation.

According to Krapohl, the solutions are rather simple: *the law and the courts*. Member States must bind the Agencies and also the Commission with substantive legal decision-making criteria, which can be enforced by the European Courts.¹⁷⁶ This means the laws need to be clear enough and not replete with concepts open to interpretation, such as “the proportionality principle” and “other legitimate concerns besides science”. Laws need to be enacted in a manner that allows Member States to truly trust the implementation with an impartial authority, and ultimately with the courts.

After discussing the roles of European level regulatory agencies, we have to mention the important regulatory role of *national regulatory agencies*. By interpreting and explaining the European and national laws in various ‘guidelines’, the *national food and medicine agencies* also create European law. For example, the Finnish Food Agency has been active in explaining to entrepreneurs how they interpret food laws. The food agency has published, among others, the following ‘guides’:

- labelling guide,
- food supplement guide,
- additive guide,
- health claim guide,
- guide on microbiological hazards of food and drinking water,
- legal guide on sports nutrition,
- requirements related to food contact materials,
- guide on sale of farm or household food,
- guide on food sales outside.

These guides can be fairly extensive compared to actual laws. For example, the guide on food supplements, updated in July 2006, has 58 pages.¹⁷⁷ In comparison, the European directive on food supplements 2002/46/EC has 7 pages, and the Finnish regulation implementing the directive has only a couple of pages. This means the rules are, from the business viewpoint, largely based on ‘the guide’. The guide on food supplements is very detailed and important issues such as the division between foodstuff and medicine are addressed. This kind of detailed advice is, by regulation targets, understood as law. The above-discussed question of combining scientific independence with democratic accountability applies also to national agencies.

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) uses the following phrase to warn people about their unreliable soft law: “This MHRA guidance should not be taken as a complete or definitive statement of the law. It is not intended as a substitute for legal or other professional advice. The MHRA accepts no responsibility for any loss or damage caused, arising directly or indirectly, in connection with reliance on the contents of this guidance.” This disclaimer is used for example in “A guide to what is a

¹⁷⁶ Krapohl 2004, 520.

¹⁷⁷ The guide is available (in Finnish) at http://www.palvelu.fi/evi/files/55_519_331.pdf.

medicinal product”¹⁷⁸ and “The Medicines Borderline Section and the Internet”. In the latter, the Agency describes its interpretation on what kind of Internet information will make the product a medicine instead of food.

Principles of democracy can, and must be, included in agency procedures. There is danger that an industry takes over a regulatory agency, which is called regulatory capture. This can happen when EU agencies or national agencies work close together with targets of the regulation, in this case food and medicine industries. As these industries are important both economically and from a human perspective, the companies and their representatives are very powerful. They are also eager to defend their own interests and demand legislation that helps make business profitable. The agencies must weigh these concerns with consumer and public health needs. Citizens need to trust that public health is kept as the guiding principle for authorities’ actions.

The basic issue of science vs. politics remains. The issue of whether food law should be based purely on science, or on “other legitimate concerns” has been debated in international arenas. Besides scientific risk assessment on threats to consumer’s health, other concerns eligible for consideration in setting food standards are economic sustainability, technological feasibility, environmental risks, consumer concerns, animal health and welfare, and ethical/religious/cultural factors. The EC generally thinks these other concerns are essential in ensuring acceptance of food law. The US generally thinks the presumption of taking into account these other concerns means opening a Pandora’s box.¹⁷⁹

2.2.3 Structure of European Food and Medicine Law

Above, we have discussed the roles of European legislators and regulatory agencies. In this chapter, we map out the outcome of their work: the framework of European law on foodstuffs and medicines. This does not include standards or self-regulation, which will be discussed below.

2.2.3.1 Foodstuffs

The basic European regulation on foods is the General Food Regulation 178/2002/EC. It includes all the general principles of European food law such as the responsibility of food industry operators, scientific risk assessment, and the precautionary principle. The General Food Regulation is referred to in other food laws. A 31-page guidance document from 2004 specifically explains certain Articles of the Regulation that have been unclear to EU food chain operators and third country trading partners¹⁸⁰.

With regard to biological safety of foods, the most important legal tool is the Regulation on the hygiene of foodstuffs¹⁸¹. The hygiene rules take particular account of the HACCP (Hazard

¹⁷⁸ MHRA Guidance Note No. 8 (previously MAL 8) April 2003.

¹⁷⁹ Poli 2004, 623-624.

¹⁸⁰ Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law. Conclusions of the Standing Committee on the Food Chain and Animal Health. 20 December 2004.

¹⁸¹ 852/2004/EC.

Analysis and Critical Control Points) principles. Chemical safety is the goal of regulations on contaminants¹⁸², residues¹⁸³, and food contact materials¹⁸⁴. Proposed regulations on additives¹⁸⁵, flavourings¹⁸⁶, and food enzymes¹⁸⁷ will guarantee the safe use of these substances. Also on novel foods, a new Regulation is emerging¹⁸⁸. A common procedure for evaluating additives, flavourings, enzymes, and novel foods will be created¹⁸⁹. GMO foods are regulated by the GMO food regulation¹⁹⁰ and the traceability and labelling regulation¹⁹¹.

Food supplements are regulated by their own directive¹⁹². It covers food supplements consisting of vitamins and minerals. Other supplements are under national law. Food fortification with vitamins and minerals is likewise regulated at EU level¹⁹³ and fortification with other substances by national laws. Dietary foods (foodstuffs for particular nutritional uses) have to comply with their own rules¹⁹⁴.

Laws on food marketing are about to change as the Commission has proposed a new Regulation on providing food information to consumers. This regulation will replace the former food labelling and nutrition labelling directives. The long-awaited regulation on nutrition and health claims in food marketing¹⁹⁵ came into force in 2007.

The above-mentioned hard law norms on foodstuffs are supplemented by various soft law documents. For example on novel foods, there is the “Commission Recommendation concerning the scientific information and the safety assessment report required”,¹⁹⁶ and on health claims, the “Scientific and Technical Guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim” by the EFSA¹⁹⁷.

2.2.3.2 Medicines

The European rules on medicinal products consist of hard law and soft law. It is almost impossible to differentiate between the two. Everything is included in “The Rules Governing Medicinal Products in the European Union”, published by the European Commission.¹⁹⁸ These rules include the following ten volumes:

¹⁸² The basic principles of EU legislation on contaminants in food are in Council Regulation 315/93/EEC. Maximum residues levels for certain contaminants in food are set in Regulation 1881/2006/EC.

¹⁸³ Maximum residue limits are set for veterinary medicinal products according to Regulation 2377/90/EC.

¹⁸⁴ The Framework Regulation 935/2004/EC sets up general requirements for all food contact materials.

¹⁸⁵ COM(2006) 428 final.

¹⁸⁶ COM(2006) 427 final.

¹⁸⁷ COM(2006) 425 final.

¹⁸⁸ COM(2007) 872 final.

¹⁸⁹ COM(2006) 423 final.

¹⁹⁰ 1829/2003/EC.

¹⁹¹ 1830/2003/EC.

¹⁹² 46/2002/EC.

¹⁹³ 1925/2006/EC.

¹⁹⁴ Directive 89/398/EEC and specific Directives on specific dietary foods.

¹⁹⁵ 1924/2006/EC.

¹⁹⁶ 97/618/EC.

¹⁹⁷ SP/NDA/CLAIMS/WD/1, Rev 4-Final.

¹⁹⁸ This collection of rules is available at: <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm>.

- Volume 1 – Pharmaceutical Legislation. Medicinal Products for Human use.
- Volume 2 – Notice to Applicants. Medicinal Products for Human use.
- Volume 3 – Guidelines. Medicinal Products for Human use.
- Volume 4 – Good Manufacturing Practices. Medicinal Products for Human and Veterinary use.
- Volume 5 – Pharmaceutical Legislation. Veterinary Medicinal Products.
- Volume 6 – Notice to Applicants. Veterinary Medicinal Products.
- Volume 7 – Guidelines. Veterinary Medicinal Products.
- Volume 8 – Maximum residue limits.
- Volume 9 – Pharmacovigilance – Medicinal Products for Human and Veterinary use.
- Volume 10 – Clinical trials. Medicinal Products for human use in clinical trials (investigational medicinal products).

Volume 1 includes directives and regulations on human medicines, which are clearly hard law, and enforceable by courts. The most important piece of law regarding human medicinal products is Directive 83/2001/EC¹⁹⁹. The 65-page directive has 127 Articles and a 40-page Annex.

The directive has fourteen Titles:

Title I: Definitions

Title II: Scope

Title III: Placing on the Market

Chapter 1: Marketing authorisation

Chapter 2: Specific provisions applicable to homeopathic medicinal products

Chapter 2a: Specific provisions applicable to traditional herbal medicinal products

Chapter 3: Procedures relevant to the marketing authorisation

Chapter 4: Mutual recognition procedure and decentralised procedure

Title IV: Manufacture and importation

Title V: Labelling and package leaflet

Title VI: Classification of medicinal products²⁰⁰

Title VII: Wholesale distribution of medicinal products

Title VIII: Advertising

Title VIIIa: Information and advertising

Title IX: Pharmacovigilance

Title X: Special provisions on medicinal products derived from human blood and plasma

Title XI: Supervision and sanctions

Title XII: Standing committee

Title XIII: General provisions

Title XIV: Final provisions.

¹⁹⁹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Official Journal L 311, 28/11/2001 p. 67 - 128).

²⁰⁰ This means classification into prescription medicines and non-prescription medicines.

The Annex of the Directive gives the analytical, pharmaco-toxicological and clinical standards and protocols in respect of the *testing* of medicinal products. The Annex refers to Commission and EMEA guidelines for further instructions.

Besides Directive 83/2001/EC, another important piece of law is Regulation 726/2004/EC²⁰¹, which includes rules of the centralised market authorisation procedure and the working rules of the EMEA.

As stated above, the directive on medicinal products does not cover all the detailed requirements for medicinal products. Guidelines are needed to complement the hard law. The need for a new guideline may be triggered by frequently encountered problems with established products, by the development of new technologies, new practices or new therapeutic areas, or by international activities²⁰². Guidelines are prepared by experts, and undergo input from academia and the industry during consultation. They are intended to be sufficiently flexible so as not to impede scientific progress.²⁰³

With Volume 2 (Notice to Applicants), the binding nature of the rules is not as clear. The Commission describes the Notice as follows²⁰⁴: “This Notice to Applicants has been prepared by the European Commission, in consultation with the competent authorities of the Member States and the European Medicines Agency. This Notice has no legal force and does not necessarily represent the final views of the Commission. In case of doubt, therefore, reference should be made to the appropriate Community Directives and Regulations.”

The Notice to Applicants was first published in 1986 and is regularly updated. It is presented in three parts:

- Volume 2A dealing with procedures for marketing authorisation;
- Volume 2B dealing with the presentation and content of the application dossier; and
- Volume 2C dealing with Regulatory Guidelines.²⁰⁵

Regulatory guidelines in Volume 2C are related to procedural and regulatory requirements such as renewal procedures, dossier requirements, summary of product characteristics (SPC), package information, readability of the label and package leaflet requirements.²⁰⁶

Volume 2B has particular status compared to other parts of the Notice to Applicants. Volume 2 B is referred to in the Annex of directive 2001/83/EC: “The particulars and documents accompanying an application for marketing authorisation ... shall be presented in accordance with the requirements set out in this Annex and *shall follow* the guidance published by the Commission in The rules governing medicinal products in the European Community, Volume 2 B, Notice to applicants, Medicinal products for human use, Presentation and content of the

²⁰¹ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Official Journal L 136, 30/4/2004 p. 1 - 33).

²⁰² Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMEA/P/24143/2004. Page 8.

²⁰³ Shah – Griffin 2003, 44.

²⁰⁴ European Commission web page: <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm>.

²⁰⁵ European Commission web page: <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm>.

²⁰⁶ Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMEA/P/24143/2004. Page 4.

dossier, Common Technical Document (CTD)).²⁰⁷ The particulars and documents “shall be presented *in strict accordance* with the format”.²⁰⁸

The Annex of Directive 2001/83/EC refers also to other parts of Volumes 2 and 3. In assembling the dossier for application for marketing authorisation, applicants *shall* also *take into account*:

- the scientific guidelines relating to the quality, safety and efficacy of medicinal products for human use as adopted by the Committee for Proprietary Medicinal Products (CPMP) and published by the European Medicine Evaluation Agency (EMA) and
- the other pharmaceutical Community guidelines published by the Commission in the different volumes of “The rules governing medicinal products in the European Community”.

Volume 3 gives *guidelines* for human medicines. As opposed to Commission regulatory guidelines, these are scientific guidelines by EMA. Guidelines are produced by the EMA Committee on Human Medicinal Products (CHMP) through its Working Parties or its membership of the International Conference on Harmonisation (ICH).²⁰⁹ The guidelines include:

- Introduction,
- Quality Guidelines,
- Biotechnology Guidelines,
- Non-Clinical Guidelines
- Clinical Efficacy and Safety Guidelines, and
- Multidisciplinary Guidelines.²¹⁰

EMA prepares scientific guidelines in consultation with the competent authorities of the Member States. Guidelines exist to “help applicants prepare marketing-authorisation applications for medicinal products for human use”. Guidelines are intended to “provide a basis for practical harmonisation of the manner in which the EU Member States and the EMA interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy contained in the Community directives”. They also “help to ensure that applications for marketing authorisation are prepared in a manner that will be recognised as valid by the EMA”.²¹¹

The role of regulatory and scientific guidelines has been clarified by “Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework”, drafted by the EMA in 2005. Previously, guidelines have also been given under the name “note for guidance”. The term “position paper” has been used on documents that reflect on issues of scientific uncertainty. In future, only the term “guideline” will be used.

²⁰⁷ Annex of Directive 2001/83/EC, Introduction and general principles, point (1).

²⁰⁸ Annex of Directive 2001/83/EC, Introduction and general principles, point (2).

²⁰⁹ Shah – Griffin 2003, 44.

²¹⁰ European Commission web page: <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev3.htm>.

²¹¹ EMA introductory note on scientific guidelines. <http://www.ema.europa.eu/htms/human/humanguidelines/background.htm>.

Distinction with respect to limited experience and/or the need for ongoing revision will be outlined within the scope of the guideline.²¹²

Guidelines are defined as follows: “In the pharmaceutical legislative framework, a guideline is a Community document that is drafted either:

- to *fulfil a legal obligation* laid down in Community legislation, or
- to *provide advice* to interested parties on the best or most appropriate way to fulfil an obligation laid down by law.”

Scientific guidelines “reflect a harmonised EU approach and are based on the most up-to-date scientific knowledge as possible”.²¹³

Guidelines are drafted via an agreed procedure including a concept paper, a draft guideline, consultation etc.²¹⁴ Comments to guidelines are expected for example from other regulatory authorities (e.g. FDA and other ICH partners), European industry associations and European scientific and academic societies, patient or consumer groups and health care professionals²¹⁵.

Guidelines may have different purposes and legal status although the general rule is that *guidelines do not have legal force*²¹⁶. The definitive legal requirements are those outlined in the EU Directives, Regulations, and Decisions, as well as national rules. However, guidelines are to be considered as *a harmonised Community position*. If they are followed by relevant parties such as the applicants, marketing authorisation holders, sponsors, manufacturers and regulators, it will facilitate assessment, approval and control of medicinal products in the EU. Nevertheless, alternative approaches may be taken, provided that these are appropriately justified.²¹⁷

Scientific guidelines are referred to in the annex to Directive 2001/83/EC and listed in the annexes to the Notice to Applicants. In assembling the dossier for an application for a marketing authorisation, applicants *shall take into account* the scientific guidelines relating to the quality, safety and efficacy of medicinal products. These guidelines are adopted by the scientific committees, such as the Committee for Medicinal Products for Human Use (CHMP) and the Committee on Herbal Medicinal Products (HMPC), and published by the European Medicines Agency (EMA). These scientific guidelines aim to provide a basis for practical harmonisation of the manner in which Member States and EMA interpret and apply the

²¹² Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMA/P/24143/2004. Page 4.

²¹³ Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMA/P/24143/2004. Page 3.

²¹⁴ Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMA/P/24143/2004.

²¹⁵ Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMA/P/24143/2004. Page 11.

²¹⁶ An exception to this rule is the “Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products”. In accordance with Directives 2001/82/EC and 2001/83/EC, this Note for Guidance has to be explicitly complied with. Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMA/P/24143/2004. Page 4.

²¹⁷ Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMA/P/24143/2004. Page 3.

detailed requirements for the demonstration of quality, safety and efficacy. They are intended to give guidance to applicants and/or sponsors in planning the overall pharmaceutical product development, as well as the non-clinical and clinical tests and studies of a compound intended to be used as human or veterinary medicinal products and to facilitate the preparation of applications for marketing authorisations by the pharmaceutical industry.

In addition to scientific guidelines the EMEA also prepares other public documents, which do not follow the procedure for guideline preparation. These are public statements, reflection papers, or “Questions and answers” documents.²¹⁸

2.2.4 Implementing the Law

2.2.4.1 About Pre-Market Control, Post-Market Control, and Penalties

Laws are void without implementation: turning them into practice and making sure they are followed. We are interested in how the rules on *safety and efficacy of foodstuffs and medicines* are controlled. Two basic alternatives are outlined here:

- a) to examine products before they enter the market (pre-market), or
- b) to examine products already on the market (post-market).

Problems with pre-market authorisations systems are that they are often time consuming, expensive, and might thus create anti-competitive barriers to or disincentives for entering a particular market. According to Philipson - Sun, a critical question in evaluating policies for regulating safety and efficacy of medicines is the optimal point in the speed-safety trade-off²¹⁹. The same question will probably be relevant also in regulating functional foods. A lengthier review process including larger clinical trials will reduce the probability that unsafe and ineffective products enter the market. Simultaneously, patients or consumers are denied access to useful products. The pre-market control agencies must search for the right balance. Pre-market control is used particularly where products pose a potentially significant risk when unsafe. Cartwright sees medicines as the most “obvious” target for pre-market authorisation.²²⁰

We also have to remember that market-based mechanisms exist to regulate safety and efficacy: products with poor evidence of safety and efficacy are less likely to be bought. This mechanism is, however, complicated by information asymmetries. In addition to questions related to demand and profitability, *product liability* (fear of litigation) gives firms incentives to provide safer products. According to studies by Philipson – Sun, *product liability might be wasteful* with medicines. This is because safety levels mandated by the regulatory bodies are higher than the firms would choose to provide under product liability alone. Still, product

²¹⁸ Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMEA/P/24143/2004. Page 13.

²¹⁹ Philipson – Sun 2008.

²²⁰ Cartwright 2001, 133.

liability imposes costs on companies, which are then included in product prices.²²¹ Product liability might thus benefit the patient or consumer in question, but not consumers in general.

Post-market control of consumer products is always necessary in spite of pre-market control. Something will always be missed in pre-market analysis, new information on raw materials and products will be discovered over time, and unethical firms will always market products with false claims. Continuous monitoring is needed to discover products that need to be taken off the market. Post-market monitoring is also important for the marketers themselves as it gives them information on how to improve their products²²². With marketing issues particularly, competitors also monitor each other's actions and report false or misleading marketing to the officials.

Penalties are here discussed as part of implementation of the rules on product safety and efficacy. Penalties are used for many different reasons and are based on different philosophies such as prevention of crimes, retribution of crimes, and incapacitation of the offenders.

2.2.4.2 Pre-Market Controls Used in Europe

2.2.4.2.1 Foods

In the EU, particular pre-market *authorisation* procedures related to foods are in place for:

- food additives and flavourings,
- novel foods,
- GMO foods, and
- nutrition and health claims.

All of the above procedures are Community procedures, meaning that the authorisation received applies in the whole EU area. According to a Commission proposal, procedures for additives, flavourings, enzymes, and novel foods will be combined in one Common procedure. Details of the procedures will be discussed below in connection to safety and efficacy requirements for each type of food products.

In addition to authorisation systems, pre-market *notification* systems exist in various Member States for food supplements, food fortification, and some of dietetic foods. Other foods can be produced and marketed without pre-market approval or notification.

For foods where no pre-market control by the authorities exists, pre-market control is still performed by the *operators themselves*. According to the General Food Regulation²²³, a food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe. Thus, food business operators have primary legal responsibility for ensuring food safety²²⁴. Food business operators at all stages of production, processing and

²²¹ Philipson – Sun 2008. These studies are on the American markets.

²²² This viewpoint is emphasized by Badea et al. 1996, page 169, as regards medical devices.

²²³ General Food Regulation 178/2002/EC, preamble 30.

²²⁴ General Food Regulation 178/2002/EC, preamble 30.

distribution shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met²²⁵.

In Finland, food control performed by the operators themselves is called *in-house control*. A food business operator must recognise food safety risks related to his activities and take responsibility for controlling these risks. For this purpose, a company must draft a written plan of in-house control, which should list critical control points where hygiene or other hazards might appear, including methods to control these hazards. These critical points include the handling of food in too warm temperatures or possible contamination. Methods of in-house control must be effective, timely, and simple.²²⁶

An international trend in food business is the weight of control shifting from authoritative control towards in-house control. This is perceived to be effective, as the food industry actor knows his own processes best. Industry operators are certifying their systems for quality control, which facilitates smoother international trade. Certified products access foreign markets easier and faster, which promotes exports and lowers costs. Operator control is thus beneficial also for the operators themselves as it enhances product safety and customer satisfaction.

With flexible laws leaving room for interpretation, regulatory agencies must be aware of not using their discretionary power in a discriminatory manner. This is the case with in-house control where the regulatory agencies have rather large discretionary powers and can, case by case, resolve whether a producer has fulfilled his in-house control obligations. In Finland, *flexibility* is seen as an important tool for judging whether self-control systems are adequate. The risk assessment rules allow the authorities to focus on most risky businesses. Intensity of official control will depend on risk classes, into which business operators are divided. The risk class is economically significant as the cost to the operators of official controls depends on how frequently the officials must visit the operator. It is, however, not clear whether and how an operator can complain about falling into a certain risk class.

2.2.4.2.2 Medicines

Medicines may be authorised in several European countries simultaneously by using one of three procedures:

- 1) the *centralised procedure*,
- 2) the *mutual recognition procedure*,
- 3) the *decentralised procedure*.

Medicines may also be authorised in a single Member State by using the *national authorisation procedure* of that country. Here we discuss only the Community procedures, in which the EMEA and the circa 40 national medicine agencies that control which medicines access the market.

We need to separately discuss new, innovative medicines vs. generic medicines. Developers of pharmaceuticals typically apply for patents that grant them exclusivity for a certain time

²²⁵ General Food Regulation 178/2002/EC, Article 17(1).

²²⁶ Finnish Food Safety Authority web page. http://www.evira.fi/portal/fi/elintarvikkeet/valvonta_ja_yritt_j_t/omavalvonta/.

period. After the expiration of patent protection, there is a new market for so called generic medicines, which are inexpensive copies of the originator medicine and have a simpler authorisation procedure.

The *European Medicines Agency (EMA)* was discussed above regarding its role in drafting the legislation on medicines. While the EMA is involved in drafting ‘hard law’, it also creates its own ‘soft law’. In addition to this, the EMA implements the law, meaning that it decides how the law is to be interpreted in single cases. Decisions applicable to private persons are subject to review by the European courts.

The EMA coordinates the evaluation and supervision of medicines in the EU²²⁷. The P most important task of the EMA is probably pre-market control of medicines. The EMA “contributes to the protection of public and animal health by ensuring that medicines for human and veterinary use are safe, effective and of high quality”²²⁸. EMA is a scientific community like EFSA. The EMA and its committees have a network of 3500 European experts²²⁹, who are involved in scientific assessment of the products. Inside the EMA, there are different committees for different types of products: the Committee for Medicinal Products for Human Use (CHMP), the Committee on Orphan Medicinal Products (COMP), the Committee on Herbal Medicinal Products (HMPC), and the Committee on Paediatric Medicinal Products (PDCO).²³⁰

The CHMP handles applications for ordinary human medicines. The COMP was established in 2001. It reviews designation applications from persons or companies who intend to develop medicines for rare diseases, so-called ‘orphan drugs’²³¹. From the end of 2004 onwards a new Committee on Herbal Medicinal Products (HMPC) will provide scientific opinions on traditional herbal medicines.²³² This latter Committee is the most interesting from our perspective, as we are developing berry-based functional food products. In 2007, a Paediatric Committee was established within the EMA²³³.

The EMA began its work in 1995, when the European system for authorising medicinal products was introduced. This system provides for a centralised and a mutual recognition procedure. The EMA also has a role in the mutual recognition procedure, but is primarily involved in the centralised procedure.

In *the centralized (Community) procedure*²³⁴, a single evaluation of the dossier is carried out through the respective EMA Committee. If the Committee concludes that quality, safety

²²⁷ According to European Union web page, the EMA also cooperates with international partners bringing EU contribution to global harmonisation. http://europa.eu/agencies/community_agencies/emea/index_en.htm.

²²⁸ European Union web page: http://europa.eu/agencies/community_agencies/emea/index_en.htm.

²²⁹ European Union web page: http://europa.eu/agencies/community_agencies/emea/index_en.htm.

²³⁰ The EMA also controls veterinary medicines. The Committee for Medicinal Products for Veterinary Use (CVMP) is not discussed here.

²³¹ Because orphan diseases are rare, there are no commercial incentives to research these diseases and develop effective therapy. The question of incentives to develop orphan drugs is related to the important issue of access to medicines. Incentives used include fee waiver, market exclusivity, and protocol assistance. Shah – Griffin 2003, 42.

²³² European Union web page: http://europa.eu/agencies/community_agencies/emea/index_en.htm.

²³³ Regulation 1901/2006/EC of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation 1768/92/EEC, Directive 2001/20/EC, Directive 2001/83/EC and Regulation 726/2004/EC. Article 3.1.

²³⁴ The centralised procedure was created by Regulation 2309/93/EEC, and its scope widened by Regulation 726/2004/EC.?

and efficacy of the medicinal product are sufficiently proven, it adopts a positive opinion, which is sent to the Commission to be transformed in a single market authorisation valid for the whole of the European Union.²³⁵ Regulation 726/2004/EC²³⁶ sets the standards as regards the centralised procedure.

For certain human medicinal products²³⁷, the centralised procedure is mandatory. These products are:

- medicinal products derived from *biotechnology and other high-technology processes*,
- medicines intended for the treatment of HIV/AIDS, cancer, diabetes or neurodegenerative diseases²³⁸, and
- designated orphan medicines intended for the treatment of rare diseases.²³⁹

For medicinal products that do not fall under any of the above-mentioned categories companies can submit an application for a centralised marketing authorisation to the EMEA, provided the medicinal product constitutes a significant therapeutic, scientific or technical innovation or the product is in any other respect in the interest of patient health.²⁴⁰ This flexibility was included by Regulation 726/2004/EC to promote EU-wide medicine research and circulation of new innovative products. Guidelines clarify which products fall under the optional scope of the Centralised Procedure²⁴¹.

The term of validity of a Community marketing authorisation is five years. Upon the expiry of this term, authorisation must be renewed. Thereafter the marketing authorisation is normally of unlimited validity. The EMEA can assess *the risk-benefit balance* of all medicinal products:

- when they are placed on the market,
- at the time of the renewal of the authorisation, and
- at any other time the competent authority deems appropriate²⁴².

Generic versions of medicinal products authorised through the Centralised Procedure will have the option of applying through either the Centralised or the Decentralised or Mutual Recognition Procedures. In practice, the Centralised procedure has been open for generic

²³⁵ European Union web page: http://europa.eu/agencies/community_agencies/emea/index_en.htm.

²³⁶ Regulation 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

²³⁷ EMEA controls also veterinary medicinal products in their own centralised authorisation procedure. This issue is not addressed here.

²³⁸ And with effect from 20 May 2008, new medicines for treatment of auto-immune diseases and other immune dysfunctions, and viral diseases. Annex of Regulation 726/2004/EC.

²³⁹ EMEA web page: <http://www.emea.eu.int/htmls/aboutus/emeaoverview.htm>. The list of medicinal products to be authorized by the Community is in the Annex of Regulation 726/2004/EC.

²⁴⁰ Regulation 726/2004/EC, Article 3(2).

²⁴¹ Human Medicines - EMEA Pre-Submission Procedural Advice. <http://www.emea.europa.eu/htmls/human/presub/q01.htm>.

²⁴² Regulation 726/2004/EC, preamble 14.

applications since 2005 when the 10-year data exclusivity periods granted to originator products, authorised through the centralised procedure, began to expire.²⁴³

The EMEA also takes the final decision in the *mutual recognition procedure*. In the mutual recognition procedure, a competent authority of one Member State (“the Reference Member State”) grants authorisation. The competent authorities of other Member States (“the Concerned Member States”) should recognise this authorisation, unless there are serious grounds for supposing that the product may present a risk to public health. A scientific evaluation of a matter is undertaken by the respective EMEA Committee, according to a Community (EMEA) standard, if Member States disagree about the quality, safety or the efficacy of a medicinal product. This evaluation by EMEA leads to a decision binding on the Member States concerned.²⁴⁴

The mutual recognition procedure has to be used by the applicant whenever an application for marketing authorisation for a medicinal product concerns two or more Member States. The mutual recognition procedure offers an important flexibility for those medicinal products intended only for a restricted part of the European market.²⁴⁵ One can exclude those countries from the procedure where markets are not interesting or where problems and opposition are suspected.

Authorisation for generic medicines is normally applied for through the mutual recognition procedure. Generic medicinal products are not required to re-perform pre-clinical and clinical trials. Even so, the documentation and data required is extensive and specific. Generics applications typically include chemical-pharmaceutical data and the results of bioequivalence studies, which demonstrate the quality and the “essential similarity” of the product. For information concerning the safety and efficacy of the molecule, the regulatory agencies are referred to the data that was established in the originator product’s application for authorisation. This is only possible once the data exclusivity period has expired on that dossier.^{246, 247}

The *decentralised procedure* came into operation in late 2005. It is applicable in cases where an authorisation does not yet exist in any of the Member States. Identical dossiers will be submitted in all Member States where a marketing authorisation is sought. The applicant chooses a Reference Member State, which prepares draft assessment documents, which are sent to the Concerned Member States. They will either approve the assessment or the application will continue into arbitration procedures. The Decentralised Procedure involves concerned Member States at an earlier stage of the evaluation than under the mutual recognition procedure. This is to minimise disagreements and to facilitate the application for marketing authorisation in as many markets as possible.²⁴⁸

Article 8 of the Directive 83/2001/EC lists *the particulars and documents that must accompany an application for marketing authorisation*. The same requirements apply to both to

²⁴³ European Generic Medicines Association web page <http://www.egagenerics.com/gen-authorisation.htm>.

²⁴⁴ Directive 83/2001/EC, preamble 12.

²⁴⁵ Reform of EU Pharmaceutical Legislation. Commission DG Enterprise MEMO/01/267. Brussels, 18 July 2001.

²⁴⁶ Directive 2001/83/EC, as amended by Directive 2004/27/EC, Article 10.

²⁴⁷ European Generic Medicines Association web page: <http://www.egagenerics.com/gen-authorisation.htm>.

²⁴⁸ European Generic Medicines Association web page: <http://www.egagenerics.com/gen-authorisation.htm>.

the centralized procedure, the mutual recognition procedure, and the decentralised procedure²⁴⁹. Annex I of the Directive 83/2001/EC contains more precise analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products. The ethical requirements of clinical trials are covered by Directive 2001/20/EC²⁵⁰.

The following research results must be included in an application:

- results of physico-chemical, biological or microbiological tests,
- results of toxicological and pharmacological tests,
- results of clinical trials.²⁵¹

Article 10 of the Directive 83/2001/EC grants procedural relief as regards *generic medicinal products*: By way of derogation from Article 8(3) (i), the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product authorised in the primary procedure at least *eight years* ago in a Member State or in the Community.” A generic medicinal product authorised according to Article 10 shall not be placed on the market until *ten years* have elapsed from the initial authorisation of the reference product.

The definition of ‘generic medicinal product’ is important here. The definition of ‘generic’ was added because the previous rules requiring ‘essential similarity’ were unclear. It is given in Article 10(2) (b):

“‘Generic medicinal product’ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.”

The current law leads to a situation where a generic is normally available to consumers after 10 years from the initial authorisation. The new EU Member States argued unsuccessfully for the period of exclusivity to last only six years. They tried this partly to protect their own generic industries, but also to preserve affordable access to medicines.²⁵²

The holder of the initial authorisation can have the ten-year exclusivity period extended to a maximum of *eleven years*. This is if, during the *first eight years* of the ten years, the

²⁴⁹ Regulation 726/2004/EC, Article 6(1) it is referred to Directive 83/2001/EC: Each application for the authorisation of a medicinal product for human use shall specifically and completely include the particulars and documents as referred to in ... Directive 2001/83/EC.

²⁵⁰ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

²⁵¹ Directive 83/2001/EC, Article 8(3)(i).

²⁵² Walley 2005.

marketing authorisation holder obtains an authorisation for one or more *new therapeutic indications*, which, during the scientific evaluation prior to their authorisation, are held to bring a *significant clinical benefit* in comparison with existing therapies.²⁵³

The rules on generic medicinal products are a compromise between important issues:

- 1) If the product is proven to be safe and effective, it is not economically sound to allocate more resources for research. There are also ethical reasons for not conducting repetitive tests on humans or animals without over-riding cause²⁵⁴.
- 2) Innovative firms should not be placed at a disadvantage²⁵⁵. There must be an adequate benefit for completing all the required tests and trials.

The *summary of product characteristics* must contain all the important information on the medicine, for example composition in terms of active substances, therapeutic indications, and undesirable effects.²⁵⁶ The generic industry complains that summary of product characteristics constitutes one of the major hurdles facing a generic medicine's application for authorisation. The generics applicant must introduce the same application file with the same summary of product characteristics in all Concerned Member States. However, originator products often have different summaries in different countries. It is thus a problem when some Member States would like the summaries of the originator and the generic to be the same.

Article 10(a) grants another relief, which is often used by herbal medicines:

“By way of derogation from Article 8(3) (i), ..., the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been *in well-established medicinal use within the Community for at least ten years*, with recognised efficacy and an acceptable level of safety In that event, the test and trial results shall be replaced by appropriate *scientific literature*.”

The requirements on safety and efficacy of herbal medicines will be discussed below in detail.

2.2.4.3 Post Market Controls in Europe

Like pre-market control, responsibility for post-market control of foodstuffs and medicines lies A) with food business operators themselves and B) with the authorities.

2.2.4.3.1 Foods

As stated above, pre-market control applies to certain foodstuffs, not all. Functional foods and other innovations have widened the area of pre-market control of foods. Novel foods and health claims are scrutinised in the pre-market arena. However, in spite of all the pre-market control activities, illegal foodstuffs commonly appear on the market. Post-market control by entrepreneurs, authorities, and by competitors and consumers is still needed.

²⁵³ Directive 83/2001/EC, Article 10(1).

²⁵⁴ Directive 83/2001/EC, preamble 10.

²⁵⁵ Directive 83/2001/EC, preamble 9.

²⁵⁶ Directive 83/2001/EC, Article 11.

According to the General Food Regulation, if a food business operator finds out it has produced or marketed a product not complying with food safety requirements, it shall *withdraw the product from the market and inform the authorities thereof*²⁵⁷. Even if the food conforms to applicable specific provisions, it can be found unsafe²⁵⁸. This might be the case if there is new scientific information on an authorised substance, or if the food contains a foreign material such as glass or metal, which is not foreseen in legislation²⁵⁹. If the product may have reached the consumers, the operator shall effectively and accurately *inform the consumers* of the reason for its withdrawal and, if necessary, recall from consumers products already supplied to them²⁶⁰. The authorities need not be informed if the operator withdraws a food that has not yet left the immediate control of the operator²⁶¹.

The General Food Regulation gives the Member States the general task of post market control. EU Member States must *enforce food law, and monitor and verify that requirements of food law are fulfilled* by food business operators at all stages of production, processing and distribution. Consequently, they shall maintain a system of *official controls and surveillance*.²⁶²

Regulation 882/2004/EC²⁶³ (the Control Regulation) gives more specific rules on how the Member States must arrange their food control systems. For example, authorities should have enough qualified and experienced staff, official controls should be regular and proportionate to the risk, procedures should be documented, and laboratories involved should comply with international standards²⁶⁴. Adequate financial resources need to be available for organising the controls, and for this purpose, Member States may levy fees²⁶⁵.

In Finland, food law implementation is the task of the Food Safety Agency. Municipal and regional authorities under the Food Safety Agency handle the inspections of facilities and products, whereas advertising is mainly supervised at a national level. Imported products are under the responsibility of the Customs. The authorities may, for example, prohibit release of goods, order labelling to be changed, or order corrective marketing. All decisions can be made more effective with conditional fines.²⁶⁶ The decisions of food control authorities can be appealed in the appropriate (regional) Administrative Court.

²⁵⁷ General Food Regulation 178/2002/EC, Article 19(1).

²⁵⁸ Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law. Conclusions of the Standing Committee on the Food Chain and Animal Health. 20 December 2004. Page 18.

²⁵⁹ Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law. Conclusions of the Standing Committee on the Food Chain and Animal Health. 20 December 2004. Page 20.

²⁶⁰ General Food Regulation 178/2002/EC, Article 19(1).

²⁶¹ Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law. Conclusions of the Standing Committee on the Food Chain and Animal Health. 20 December 2004. Page 18.

²⁶² General Food Regulation 178/2002/EC, Article 17(2).

²⁶³ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

²⁶⁴ Preambles 11, 13, 14, and 15 of the Regulation, respectively.

²⁶⁵ Preamble 32 of the Regulation.

²⁶⁶ The Finnish Foodstuffs Act 23/2006, section 7.

The EU further controls the enforcement and control activities of Member States. As the guardian of the European Community Treaties, the Commission is responsible for ensuring that Community legislation on foodstuffs is properly implemented and enforced.²⁶⁷ The Commission has a special task unit, *the Food and Veterinary Office (FVO)*,²⁶⁸ which evaluates compliance with EU standards and works to make control systems more effective.

The main task of the FVO is to carry out *inspections* in Member States and in third countries that export foodstuffs to the EU. Each year they develop and publish an inspection program, identifying priority areas and countries for inspection.²⁶⁹ The results of each inspection are published in an inspection report, together with conclusions and recommendations.²⁷⁰ The FVO makes recommendations to the country's food control authority to deal with shortcomings revealed during the inspections.

For example on 10 May 2007, the FVO published their reports on Latvian potatoes, Indian fishery and aquaculture products, Nicaraguan fishery products, pesticides in Moroccan plant products, and UK import controls and border inspection posts. The Member State authority is requested to present an action plan to the FVO on how it intends to address the discovered problems. The FVO evaluates this plan and monitors its implementation through follow-up.²⁷¹

In addition to reports on each inspection, the FVO produces summary reports on series of inspections to several Member States on the same subject, and their annual report. *The FVO also has a role in developing EU food law*, and where appropriate, the FVO may in their inspection reports point out areas where legislation is unclear, not functioning properly, or missing. The Commission may take these findings into account when drafting new legislation.²⁷²

If the Member States fail to control foodstuffs, the EU Commission can revert to Article 226 procedures²⁷³ of the EC Treaty, and ultimately take the matter to the European Court of Justice. According to Inglis, the Internal Market safeguard clauses of the Accession Treaties give the Commission a more effective instrument regarding the new Member States that joined the EU in 2004. The Commission has wide discretionary powers to take action against new Member States and force them to comply with the EU laws.²⁷⁴

2.2.4.3.2 Medicines

It was stated above that pre-market control is the dominant regulatory mechanism for medicines. In spite of very detailed pre-market control procedure with specified requirements,

²⁶⁷ European Commission web page: http://ec.europa.eu/food/fvo/index_en.htm.

²⁶⁸ The FVO is part of the DG SANCO (Directorate-General for Health and Consumer Protection) and it is based in Ireland. The number of its staff is 163 in May 2007, half of which are on-the-spot inspectors. http://ec.europa.eu/food/fvo/how_en.htm.

²⁶⁹ European Commission web page: http://ec.europa.eu/food/fvo/how_en.htm.

²⁷⁰ The food control authority of the country visited may comment on the inspection reports at their draft stage. http://ec.europa.eu/food/fvo/how_en.htm.

²⁷¹ European Commission web page: http://ec.europa.eu/food/fvo/how_en.htm.

²⁷² European Commission web page: http://ec.europa.eu/food/fvo/how_en.htm.

²⁷³ "If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations. If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice." Article 226 of the EC Treaty.

²⁷⁴ Inglis 2004, 608.

post-market control is also needed. Post market control is needed to take illegal medicines off the market, and to tackle illegal medicinal product advertising. In addition, post market control is needed to take products off the market that have originally been authorised but later been uncovered as unsafe or ineffective.

Post-market control is performed by *entrepreneurs* and by *authorities*. Member States may also impose specific requirements on *doctors* and other health care professionals in respect of the reporting of suspected serious or unexpected adverse reactions, in particular where such reporting is a condition of the marketing authorisation.²⁷⁵ *Consumers* are also encouraged to report side effects of medicines.

Member States must supervise the observance of good manufacturing, laboratory and clinical practices. Member States must inform the relevant EMEA Committee and the Commission of all instances where a manufacturer or importer fails to fulfil its obligations.²⁷⁶ For medicines authorised in the mutual recognition procedure, decentralised procedure, or national procedure, the national authorities may revoke product licenses or order a marketer to stop marketing illegal medicinal products. In Finland, the authority responsible for post-market control is the National Agency of Medicines. For medicines authorised through the Centralised Procedure, the EMEA may introduce amendments to the marketing authorisation, and reassess the risk-benefit balance of the product at any time²⁷⁷. These actions lead to withdrawal from the market of any medicinal product presenting a negative risk-benefit balance under normal conditions of use²⁷⁸.

Pharmacovigilance means monitoring and reporting of undesirable effects of medicinal products. It falls under the responsibility of operators and authorities. Member States must have a pharmacovigilance system in place, and the EMEA is responsible for coordinating Member States' pharmacovigilance activities. The pharmacovigilance system shall be used to collect information useful in the surveillance of medicinal products, with particular reference to adverse reactions in human beings, and to evaluate such information scientifically. Information on misuse and abuse of medicinal products shall also be taken into account.²⁷⁹

The marketing authorisation holder shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance. This person shall make sure that all information about adverse reactions received by the company is gathered and accessible at least at one point within the Community. This person shall also prepare reports to the authorities and provide the authorities all the necessary information for the evaluation of the medicinal product.²⁸⁰

2.2.4.4 Penalties Used in Europe

According to the General Food Regulation, Member States of the EU shall lay down the rules on measures and penalties applicable to infringements of food law. The measures and

²⁷⁵ Medicinal Products Directive 83/2001/EC, Article 101.

²⁷⁶ Regulation 729/2004/EC, preamble 31.

²⁷⁷ Regulation 729/2004/EC, preamble 30.

²⁷⁸ Regulation 729/2004/EC, preamble 29.

²⁷⁹ Medicinal Products Directive 83/2001/EC, Article 102.

²⁸⁰ Medicinal Products Directive 83/2001/EC, Article 103.

penalties provided for shall be effective, proportionate and dissuasive.²⁸¹ It is similarly stated in medicine law that Member States must determine penalties that are effective, proportionate and dissuasive.²⁸² EU Member States consider fines and/or imprisonment as penalties for breaking the rules on safety and efficacy/marketing or foodstuffs or medicines. In some Member States, the penalties are more stringent than in others. Contrary to the Chinese practice, no precise euro amounts of fines are stipulated by legislation. Instead, penalties are defined case by case by courts on various levels. Criminal responsibility will be invoked only in exceptional cases, as the authorities will endeavour to settle any breach of the regulations by negotiation or other out-of-court procedures. They may for example issue prohibitions or information orders as discussed above.

In Finland, foodstuff misdemeanour is defined in the Food Act, section 79. Foodstuff misdemeanours are minor acts contrary to the Food Act, which do not directly cause danger to people's health. This means for example omission of a notification duty, or failure to draft a written plan for in-house control. Selling foodstuffs that do not comply with food law requirements, and are possibly hazardous to health, constitutes *health offence* according to the Finnish Criminal Code, chapter 44, section 1. a *medicine offence* is defined in chapter 44, section 5 of the Finnish Criminal Code. Possible Finnish punishments for breaking the European or Finnish medicine laws or decisions based on these laws are a fine and a maximum of one-year imprisonment.

Poisoning foodstuffs or selling poisonous foodstuffs and thus causing a public health hazard constitutes *endangerment of health*, chapter 34, section 4, or *gross endangerment of health*, chapter 34, section 5. The punishment for a health offense is a fine or a maximum of six months' imprisonment, for endangering health, four months to four years' imprisonment, and for gross endangerment of health, from two to ten years' imprisonment. Giving false or misleading marketing information constitutes a marketing offense according to chapter 30, section 1. The punishment for a marketing offense is a fine or a maximum of one-year imprisonment. The applicable criminal penalties when violating marketing regulations are usually of limited size, a few thousand euros.

An example of a functional food -related case is *Market Court, MT 1993:023, 9.11.1993, Ombudsman vs. Valio Oy* where the Finnish company Valio was prohibited from using the claim that milk cures/relieves/prevents osteoporosis. There have also been a few cases where health claims have been used in an inappropriate way in the marketing of dietary supplements, for example *MT:1993:008: PSK-Javidos Ab. vs. Vitabalans*, which related "high potency garlic". There was also a flagrant case in 1998 where the Food Agency prohibited the selling and importing of Noni Juice. The seller claimed that the product cures cancer, HIV, diabetes, rheumatism etc.

In addition to criminal cases, civil cases for damages may be taken to courts on various levels. Damage might be caused to a consumer by unhealthy food or misleading food advertising. There are some differences in EU Member States concerning burden of proof. According to general legal principles applicable in most Member States, the burden of proof lies with the plaintiff. In practice, this creates financial problems to consumer associations and also to authorities wishing to claim against a manufacturer. It requires enormous resources to

²⁸¹ General Food Regulation 178/2002/EC, Article 17(2).

²⁸² Regulation 726/2004/EC, Article 84(1). Directive 83/2001/EC, Article 99.

prove scientific facts about a product.²⁸³ However, where a pre-market authorisation procedure exists, the burden of proof is always on the producer. This applies to safety of novel foods and substantiation of marketing claims.

The use of unsafe or ineffective medicines may often lead to personal and financial damage. Medicines are always somewhat unsafe, in a sense that they have side effects. This is one of the most important differences compared to foodstuffs. In most European countries including Finland, *pharmaceutical injuries insurance* covers certain severe²⁸⁴ *unexpected* adverse effects sustained by users of pharmaceuticals. The insurance covers pharmaceuticals manufactured, imported or marketed by companies who are members of The Finnish Cooperative for the Indemnification of Medicine-Related Injuries. The insurance is voluntary for the pharmaceutical companies. The insurer is the Finnish Pharmaceutical Insurance Pool, which is made up of three insurance companies. The Finnish Pharmaceutical Insurance Pool handles the claims and pays accepted claims.

The insurance only covers personal damage, not financial losses.²⁸⁵ In addition, the insurance leaves important areas outside its scope. It does not cover: an injury resulting from *medically necessary risk taking*, injuries where the adverse effect of the pharmaceutical is *reasonably tolerable*, insignificant injuries, or failure of the drug to have the intended effect (inefficacy).²⁸⁶ Injuries resulting from use of illegally acquired medicines or misuse of medicines are not covered by the insurance, neither are injuries caused by herbal and homeopathic medicines. These restrictions might lead to the situation where only serious injuries caused by medicines taken for minor diseases are covered by the insurance. For damages other than those covered by the insurance scheme, a lawsuit against the pharmaceutical company is needed.

If there is nothing wrong with the medicine itself, but it has been incorrectly prescribed or administered by a doctor or pharmacist, the injury is not covered by the pharmaceutical injuries insurance. In that case, the injury may be compensable under the Patient Injuries Act. The patient injury insurance is mandatory for hospitals etc.

2.2.5 European Standards

Formal standardisation in Europe has a three-level structure, which includes the national standards bodies (NSB's), the three European Standards Organisations (ESO's), and the international organisations discussed above. The ESO's have been formally recognised by the EU by Directive 98/34/EC. These are: CEN²⁸⁷ for the majority of sectors, CENELEC²⁸⁸ for the electro-technical area, and ETSI²⁸⁹ in telecommunications. In addition, there are a multitude of

²⁸³ Hill & Knowlton 2000, 18.

²⁸⁴ To qualify for compensation under pharmaceutical injuries insurance, use of pharmaceutical must result in a loss of functional ability lasting at least 14 days without interruption or in a permanent physical injury or illness or death. Finnish pharmaceutical insurance pool website www.lvp.fi.

²⁸⁵ Finnish pharmaceutical insurance pool website www.lvp.fi.

²⁸⁶ Finnish pharmaceutical insurance pool website www.lvp.fi.

²⁸⁷ Comité Européen de Normalisation. European Committee for Standardisation.

²⁸⁸ Comité Européen de Normalisation Electrotechnique. European Committee for Electrotechnical Standardisation.

²⁸⁹ European Telecommunications Standards Institute.

informal standards bodies²⁹⁰ and of CEN standards for foods, mainly for methods of sampling and analysis²⁹¹.

According to the Commission, standards are an integral part of EU policies. Standards are expected to increase competitiveness of enterprises, and to remove barriers to trade at international level. They are also seen as part of “better regulation”. According to the Commission, European standardisation has proven to be a successful tool for the completion of the Single Market for goods.²⁹² Standards are seen as playing *a supportive role* in legislative acts and projects related to goods, services, environment, and consumer protection²⁹³. According to Schepel, the Commission is holding on to the fiction that compliance with European standards is strictly voluntary. Instead of redefining law, hard law is trying to defend its monopoly as the only source of mandatory commands.²⁹⁴

The Commission has presented the “New Approach” as a specific model of legislation where public interest and the interest of private business could be merged. It allows for “more flexible and less stringent forms of legislation” in areas where there is a great need for detail. As legislation needs to be simplified, the extension of use of standards beyond the goals of the Single Market is seen as “highly desirable”.²⁹⁵ The Commission acknowledges that standardisation is “independent and market driven”, but strongly encourages standards organisations to further develop standardisation procedures.²⁹⁶ In 2006, the EU created a legal basis for the financing of European standardisation²⁹⁷. The Commission saw this as “a contribution from the EU side to add value to standardisation in the context of EU policies”²⁹⁸. The EU is enthusiastically supporting standards development, and willing to replace law with standards, as long as standards are not called ‘law’.

In a society, people *share attitudes* towards risk and technology, reflecting a widely respected professional ‘common sense’. These shared attitudes make standards, which link socially accepted behaviour with legally institutionalised requirements. According to Schepel, European standardisation needs to focus on mechanisms for social construction of common sense, because Europeanisation uproots standards from their (national) social beddings.²⁹⁹ This general question of central vs. local legislation is ultimately about whether a member can trust the coalition, union, central government, or global actor, etc. to promote the interests of all its members.

²⁹⁰ Commission Communication on Standards 2008, 3.

²⁹¹ CEN webpage at: <http://www.cen.eu/cenorm/sectors/sectors/food/index.asp>.

²⁹² Commission Communication on Standards 2004, 2.

²⁹³ Commission Communication on Standards 2004, 3.

²⁹⁴ Schepel 2005, 406.

²⁹⁵ Commission Communication on Standards 2004, 4.

²⁹⁶ Commission Communication on Standards 2004, 3.

²⁹⁷ Decision No 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation.

²⁹⁸ Commission Communication on Standards 2004, 3.

²⁹⁹ Schepel 2005, 144.

2.2.6 Self-Regulation

Since the first half of the 1990's, the EU Commission has been active in establishing a completely new framework of food law. It can be argued that food legislation is not only getting increasingly complicated, but it is also becoming stricter as more areas are covered. *The European food industry has attempted to hold back the tide of legislation*³⁰⁰, and instead favours self-regulation.

The most important actor speaking for self-regulation is the CIAA, Confederation of the Food and Drink Industries in the EU.³⁰¹ CIAA calls for simpler, clearer legislation and shorter, less burdensome legal procedures. According to the CIAA, the food and drink industry is one of the most regulated sectors in Europe. They claim "better regulation, including industry self-regulation, can deliver benefits to European consumers faster and help to promote higher growth and employment". They are working for "a better functioning single market, fewer administrative burdens, and a more supportive business environment". According to the CIAA, this is needed particularly to help small and medium-sized companies.³⁰²

The CIAA considers that "many of the problems faced by the food and drink industry with existing legislation should be solved through a better, simpler, more proportionate and a more competitive EU regulatory framework". They recommend the following principles on food law:

- Legislation must be *clear* to prevent diverging interpretation,
- Legal requirements must be practically *achievable and enforceable*,
- Legislation must be based on *science*,
- Procedures must be *clear and predictable*, including precise timetables,
- Sufficient *lead-in times*, where possible, are needed to minimize implementation costs.³⁰³

To support their argument that self-regulation is a viable alternative, the CIAA has indeed drafted numerous documents that can be classified as soft law. The CIAA has for example created a voluntary nutrition labelling scheme. They claim that revision of the nutrition labelling Directive should be started by considering what self-regulatory initiatives have already delivered³⁰⁴. This means some legal requirements could be deleted as unnecessary, and the remaining legal requirements should be simplified.³⁰⁵

The food industry's concerns and suggestions need to be taken seriously by the Commission. In particular, the regulatory procedures should be transparent and not waste the efforts of all the parties involved. However, the food industry might not actually *want* to understand all the substantial laws as some of the complicated and inconveniently strict laws are burdensome. By demanding 'simple', we suspect that they simultaneously wish for 'less restrictive'.

³⁰⁰ ElAmin 2006b.

³⁰¹ CIAA membership is made up of 25 National Federations, including 3 observers, 30 EU sector associations representing different food industry sectors, and 20 major food and drink companies.

³⁰² http://www.ciaa.be/pages_en/homepage.asp.

³⁰³ Review of CIAA Priorities and Objectives for Better Regulation in light of the Commission proposals to simplify EU legislation. CPT/003/07E-Final Brussels, 28 February 2007. Page 5.

³⁰⁴ Review of CIAA Priorities and Objectives for Better Regulation in light of the Commission proposals to simplify EU legislation. CPT/003/07E-Final Brussels, 28 February 2007. Pages 2-3.

³⁰⁵ Ibid, page 3.

Also national self-regulation on foods exists. For example in Finland, the food industry and the retail trade drafted (in 2003) their recommendations on good practices and recommended temperatures and sales times for fresh meat and fish. The recommendations included that operators agreed to use lower storage temperatures than required by the law. This was considered by the Ministry of Trade and Industry to be “a very good project”.³⁰⁶ Self-regulation can work well if operators are committed into achieving a common goal like unhealthy competition.

ElAmin claims that the industry should take self-regulation much more seriously if they want the legislators to step aside. The industry organizations are giving vague promises that they will follow a common line over issues such as advertising, obesity, health claims and nutritional content. If they really believe their own codes could be used instead of EU legislation, they should take up the challenge and actually draft these codes.³⁰⁷ Irresponsible companies cannot be given the responsibility of Europeans’ health.

General problems with self-regulation relate to unclear responsibilities, freeriders, implementation and control, and restricting competition³⁰⁸. Interests of dominant companies might outweigh public and societal interests³⁰⁹. Future business regulation might increasingly be in the form of *co-regulation*, combining the benefits of law and self-regulation³¹⁰. According to Parker and Braithwaite, it is necessary to understand how law connects with other sources of normative ordering³¹¹. Regulation is pluralised and decentralised, and the new role of states is to steer public-private partnerships³¹².

2.3 Chinese Law on Foodstuffs and Medicines

2.3.1 Rule of Law in China

When discussing Chinese law, concepts such as state, law, or court must not be presumed to mean the same as in due to the fact that history and contemporary understanding of law in the Chinese society is different from ours. An outright hostility towards law in a Western sense is inherent in Chinese history and culture. According to Confucius, what is needed is a situation where there are no legal cases³¹³. China started to create a legal system and law in a Western sense at the end of the 1970’s, in conjunction with its new open-door policy. In China, law was traditionally seen as an instrument of governance for the rulers, and ‘rule of man’ was applied instead of ‘rule of law’³¹⁴. There was law, but it was occupied with implementing the Emperor’s orders, and did not relate to agreements or disagreements between citizens, or rights of citizens. There was in fact no such thing as a citizen: people were subordinates.

China has created large volumes of legislation in the past 30 years. However, laws are void without implementation. After writing the necessary positive laws, China has to create legal

³⁰⁶ Ministry of Trade and Industry. <http://www.ktm.fi/index.phtml?s=1031>.

³⁰⁷ ElAmin, Ahmed 2006c.

³⁰⁸ Tala 2009, 330-331.

³⁰⁹ Tala 2009, 330.

³¹⁰ See Tala 2009, 331-332 on benefits and problems of co-regulation.

³¹¹ Parker – Braithwaite 2005, 137.

³¹² Parker – Braithwaite 2005, 129.

³¹³ Jones 2003, 7. Here Jones cites Bodde – Morris 1967.

³¹⁴ Kobayashi 2008, 3.

institutions to make law work in practice. The legal reform is closely connected to the *economic transition*. Government agencies are no longer primarily responsible for managing economic entities or planning their economic transactions. In the new economic order, it is enterprises and individuals and their relationships that are important. Private actors must believe that they will be held to their legal obligations, and that their legal rights will be protected. As the government can no longer command market actors to make economic decisions, it needs the ability to use administrative sanctions, and the ability to resort to courts.³¹⁵ *Instead of command, the market now needs to be guided through law.*

This leads us to the concept “rule of law” and the discussion on modern Chinese law that revolves around this concept. Several scholars are discussing the development, current level, and future direction of rule of law in China³¹⁶. Building the rule of law has been on the Party agenda since the mid-1990s, and the Constitution was amended in 1999 to include the concept³¹⁷. It states in the Constitution that all agencies, administrators and enterprises must abide by law, all acts in violation of the law must be investigated, and that no one is above the law³¹⁸. These are rather familiar concepts to Europeans, but novel to the Chinese.

There are narrow and wide concepts of rule of law. The narrow concept is rather formal and requires the very basic parts of the legal system to exist, meaning significant restraints on the use of powers, supremacy of law, and equality of citizens before the law. In a society governed by rule of law, laws need to be general, public, prospective, clear, consistent, and capable of being followed, stable, and enforced. Some insist the rule of law must include liberal democracy and human rights, and wider theories add political, social, and economic concepts. Some writers are of the view that China fulfils the narrow criteria. Some argue that China is a country of rule *by* law at best: law is used by the non-democratic state as an instrument for social control.³¹⁹ Peerenboom sees China as following the ‘East Asian model’, where economic growth, legal reforms, democratization, and constitutionalism follow each other, in this order³²⁰.

According to critics, China is far from achieving the rule of law. The Congress needs to be strengthened as legislator, the Constitution should be enforced, and the judiciary should be independent. Corruption is common among public officials: personal favours, bribery, and the taking of public monies happen at all levels of government. The legal profession has also been inadequate and China is now putting effort into training competent judges and attorneys.³²¹ The

³¹⁵ Lichtenstein 2003, 287.

³¹⁶ See the Rule of Law in China program at the Foundation for Law, Justice and Society, a think-tank affiliated with Oxford University’s Centre for Socio-Legal Studies. The scholars in this program have written several articles in English on rule of law in China, both generally and as regards certain legal areas such as employment or intellectual property. See Foundation for Law, Justice and Society at <http://www.fljs.org>. See rule of law in China publications at <http://www.fljs.org/section.aspx?id=607>.

³¹⁷ Wikipedia: http://en.wikipedia.org/wiki/Chinese_law.

³¹⁸ Article 5 of the Constitution.

³¹⁹ Qingjian 2002, 301, uses the words “rule through law”. See also Wikipedia: http://en.wikipedia.org/wiki/Chinese_law. Wikipedia article sites Randall Peerenboom: *China’s Long March Toward Rule of Law*, Cambridge University Press 2002, and Albert Huhg-yeen Chen: *An Introduction to the Legal System of the People’s Republic of China*, 1992.

³²⁰ Peerenboom 2008, 6.

³²¹ Wikipedia: http://en.wikipedia.org/wiki/Chinese_law. Article sites Randall Peerenboom: *China’s Long March Toward Rule of Law*, Cambridge University Press 2002, and Albert Huhg-yeen Chen: *An Introduction to the Legal System of the People’s Republic of China*, 1992.

legal reform revolves around taking some of the powers away from administrators, who up until now have been the legislators, the executors, and the judges.

According to Peerenboom, China's performance on rule of law might be best judged in relation to other countries in its income class³²², and China seems to be doing reasonably well by that measure³²³. In addition, there is also critique on the whole discussion on the rule of law in China. According to Jerome Cohen, the problem with Westerners is that we never go beyond that primitive stage we call the rule of law, and China has always known that law is not enough to govern a society.³²⁴ According to Qingjiang, *guanxi* (social connections) and *mianzi* (face) do still affect implementation of laws in China³²⁵.

We are of the view that the mere existence of laws, even laws of technically high quality, is not a goal in itself and guarantees nothing more than clarity on paper. The content, substance of law, is what matters along with the need to address the requirements of companies and individuals. It is therefore essential that stakeholder voices are heard before making laws, and essential that laws be implemented in practice. Disputes need to be fairly resolved, whether by courts or by other means such as mediation³²⁶.

2.3.2 Hard law and Administrative Soft Law

In China, there is a similar situation compared to the EU: the issue of legislative competence of central government versus the competence of provinces and cities. In Europe, it is a question of EU laws vs. Member State laws, and in China it is a question of national laws vs. local laws. Also the question of hard law vs. soft law is relevant in China. Various administrative bodies issue regulations and guidelines on food and medicine issues.

In China, the Constitution is not an important part of law, and according to Clarke, it does not represent anything, and is perhaps the least important document in the entire legal system³²⁷. In reality, the Chinese government does not work in the way described in the Constitution.

In theory, the *Chinese central government is strong* with powerful instruments at its disposal. All the powers of localities stem from the centre³²⁸. The central government decides who controls the provinces: It appoints the government top officials and the party top officials in the provinces. The central government also controls key economic resources like scarce raw materials, government investments, foreign loans and budgetary subsidies. Unity of the nation and thus strong central government is also culturally favoured: the Han majority of people want to see China as one.³²⁹ In practice, Chinese localities have been given powers and resources to administer the state economy in those localities. Driven by local interests, local

³²² Wealth is highly correlated with good governance indicators, human rights, and other indicators of human well-being.

³²³ Peerenboom 2008 a, 5.

³²⁴ Cohen according to Jones 2003.

³²⁵ Guanxi can work both ways: it can either assist in enhancing law enforcement, or be used to avoid compliance of law. Similarly, law enforcement may also be related to the psychological assessment of saving face or losing face of the persons against whom law is enforced. Qingjiang 2002, 301.

³²⁶ Lichtenstein 2003, 288.

³²⁷ Clarke 2003, 103.

³²⁸ Qingjiang 2002, 305.

³²⁹ Ren 2000, 102-103.

leaders have gradually become less obedient to the centre, and centrally promulgated laws are unevenly implemented at local level.³³⁰

Officially, the highest governing body in China is the parliament, the *National People's Congress*. The amount of representatives has fluctuated between 2000 and 3500 members. Representatives are chosen by indirect election. Local congresses elect the members of provincial congresses, and provincial congresses elect the members of the national congress. The authorities of the Parliament are extensive. The Parliament enacts the national laws and appoints the prime minister, other ministers, and the president. The NPC also decides on the state economic plans and budgets.³³¹ The role of the parliament has increased in the recent years.

The NPC chooses among itself a Standing Committee that convenes the parliament, *issues regulations*, interprets laws, and oversees government activities. The chairman of the Standing Committee acts as the chairman of the parliament.³³² The National Congress, which is led by the prime minister, appoints the members of the State Council, which is the highest executive organ in China, as well as the highest organ of State administration³³³. The position of the Party has normally been decisive in choosing the members of the State Council³³⁴.

According to the Constitution, the state and the communist party work together to rule the country. Since the birth of the People's Republic in 1949, the Chinese communist party (*Zhongguo gongchandang*) has been in a central role in state affairs.³³⁵ Officially and formally, there are also other parties and citizen organisations in China, but their influence is not significant.³³⁶ The real locus of central political power in China lies in the leadership of the Communist Party, which exercises power largely through the State Council. The party has inherent authority to make rules about anything. For a number of reasons, it now chooses to make certain rules through the National People's Congress.³³⁷

The Party has a leading role in central and local government, the army, and economy. *Party agencies make decisions and issue them to state agencies for implementation*. Party control maintains a broad reach: the division of power between the Party and the State is not definitive. In principal, the Party is to efficiently maintain large issues, but in practice, it also involves itself in smaller issues. The same people work for the state and the party: party representatives have leading positions also in state government.³³⁸

Below the central level, there are both sectorally defined ministries and geographically defined provincial authorities.³³⁹ Geographically, China is divided into provinces³⁴⁰,

³³⁰ Qingjiang 2002, 305.

³³¹ Huotari – Seppälä 1993, 128-129.

³³² Huotari – Seppälä 1993, 129.

³³³ Official web page of the Central People's Government of the People's Republic of China. http://english.gov.cn/2008-03/16/content_921792.htm.

³³⁴ Huotari – Seppälä 1993, 130.

³³⁵ Preamble of the Constitution, see also Amendment 2 of 1993 and Amendment 3 of 1999. Huotari – Seppälä, 124.

³³⁶ Huotari – Seppälä 1993, 123.

³³⁷ Clarke 2003, 111.

³³⁸ Huotari – Seppälä 1993, 124.

³³⁹ Weixin 1992, 48-49.

³⁴⁰ Hebei, Shanxi, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Fujian, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Hainan, Sichuan, Guizhou, Yunnan, Shaanxi, Gansu, Qinghai, and Taiwan.

autonomous regions³⁴¹, special administrative regions³⁴², and municipalities directly under the central government³⁴³. Provinces and autonomous regions are further divided into autonomous prefectures, counties, autonomous counties and cities, and counties are divided into towns and townships.³⁴⁴ Local and provincial legislation is given by local and provincial congresses. According to the Constitution and the 2000 Act of Legislation, the NPC Standing Committee oversees local regulations, and can annul any local regulations contravening the Constitution or national laws³⁴⁵. In practice, however, this responsibility is far from being realised, and a large number of local regulations contravene national laws³⁴⁶. According to Weixin, the Chinese economy is not actually integrated, even though China is a centrally planned economy with one central government and one currency in circulation. There are barriers to the mobility of goods and there is a lack of economic cooperation and specialisation within China. The administrative frontiers are also economic frontiers.³⁴⁷

The sectoral planning hierarchy also fragments the market. All sectors within the economy are organised vertically and headed by ministries under the State Council. Ministries include the Ministry of Health, the Ministry of Agriculture, and the Ministry of Science and Technology³⁴⁸. The Ministry of Health is the most relevant in regulating foodstuffs and medicines. Also the *State Food and Drug Administration (SFDA)*³⁴⁹, founded in 2003, has its role in drafting various guidelines related to safety and efficacy of foodstuffs and medicines³⁵⁰. According to Bian, the SFDA is lacking in authority because it has to co-ordinate among several ministries that have a higher administrative rank³⁵¹. The SFDA is at the moment directly under the State Council³⁵², but will be transferred under the Ministry of Health in the upcoming government restructure, see below.

Regulations that can be enacted by ministries are called *guizhang*. These regulations tend not to be results of comprehensive planning or strategy. They are rather reactions to problems arisen. Within the areas of food and medicines, several different government agencies have competence to regulate and supervise the entrepreneurs. When giving *guizhang* regulations,

³⁴¹ Inner Mongolia Autonomous Region, Guangxi Zhuang Autonomous Region, Tibet Autonomous Region, Ningxia Hui Autonomous Region, and Xinjiang Uygur Autonomous Region .

³⁴² Hong Kong Special Administrative Region and Macao Special Administrative Region.

³⁴³ Beijing, Tianjin, Shanghai, and Chongqing.

³⁴⁴ Weixin 1992, 47.

³⁴⁵ Jian 2003, 506-507.

³⁴⁶ Jian 2003, 508.

³⁴⁷ Weixin 1992, 47.

³⁴⁸ There are altogether 28 Ministries and Commissions under the State Council. In addition, there are at least 36 other organisations and institutions directly under the State Council. These include the Customs, the Bureau of Statistics, and the Intellectual Property Office. Government's official web portal: <http://english.gov.cn/links.htm#1>. See plans on restructuring the State Council at GOV.cn: Tuesday, 11 March, 2008. http://english.gov.cn/2008-03/11/content_916738.htm.

³⁴⁹ The State Food and Drug Administration was founded according to the restructuring plan of the State Council, approved by the First Plenary Session of the 10th National People's Congress, and "the State Council Notice on Government Structuring", No.8.2003. The new authority replaced the former State Drug Administration. <http://www.sfda.gov.cn/cmsweb/webportal/W43879538/index.html>.

³⁵⁰ The SFDA has control over foods, medicines, and cosmetics. Its domain is thus similar to that of the FDA in the United States. In Europe, food and medicine administration is divided under two separate agencies at the EU level and also in most EU Member States.

³⁵¹ Bian 2004.

³⁵² SFDA web page at: <http://www.sfda.gov.cn/cmsweb/webportal/W43879538/index.html>.

administrative organs do not necessarily check whether their guizhang is in agreement with laws or former regulations by the same administrative organ or other administrative organs. Thus, conflict among guizhang provisions is not rare.³⁵³ This is naturally confusing both to regulation targets and those that are supposed to supervise them.

Legal and economic integration of China cannot be realised at once due to the participants being separated both geographically and by sectors. The Chinese have created Economic Zones as a type of regional economic experiment.³⁵⁴ The establishment of these zones is to encourage economic cooperation by promoting the division of labour and competition like in the EU.³⁵⁵ These are the first steps towards integration of the Chinese economy. According to Weixin, the successful realisation of regional integration in China requires institutional arrangements similar to those of the EU. Interests of the whole economy and the individual economies need to be coordinated. The decision-making procedures are important in this respect.³⁵⁶

According to Article 90 of the Chinese Constitution, “the ministries and commissions issue orders, directives and regulations within the jurisdiction of their respective departments and in accordance with the statutes and the administrative rules and regulations, decisions and orders issued by the State Council”. The Ministry of Health has the competence to legislate on the area of foodstuffs and medicines.

The SFDA, on the other hand, does not have hard-law legislative power. However, the SFDA’s Department of Policy and Regulations, Division of Regulations, has the following tasks:

- “studying and drafting legislation program and annual plan for food and drug administration;
- participating in, and/or organising the drafting of Medicine Administration Laws and regulations;
- organising relevant authorities to draft laws and regulations for safety management of food, health food and cosmetics
- organising and carrying out review, coordination and issue of administrative provisions;
- interpretation of the related laws and regulations in accordance with law”.³⁵⁷

This means the SFDA is at the moment involved in both important stages of food and medicine law: preparing and implementing the laws. The SFDA plans and drafts legislation promulgated by the Ministries under the State Council. The Authority also provides its own administrative regulations, and interprets laws and regulations.

The division of work between the Ministry of Health and the SFDA will be restructured in the future. According to information on the central government’s website in March 2008, China is upgrading the Ministry of Health to better monitor the safety of foodstuffs and medicines. The SFDA will be transferred under the Ministry of Health. The “new MOH” will be authorised to coordinate food safety management, organise investigations into serious food safety incidents, and give “due punishment”. *The MOH is responsible for the constitution of the national food*

³⁵³ Bian 2004.

³⁵⁴ Weixin 1992, 88.

³⁵⁵ Weixin 1992, 91.

³⁵⁶ Weixin 1992, 86.

³⁵⁷ SFDA web page. <http://www.sfda.gov.cn/cmsweb/webportal/W44993659/index.html>.

and medicine laws. The SFDA, after the reform, is responsible for food sanitation permits, monitoring food businesses, and monitoring the safety of medicines including their research, production, circulation, and use.³⁵⁸ This means that in the future, the MOH will be giving all the laws on foodstuffs and medicines, not the SFDA. The task of the SFDA will be to more efficiently monitor the businesses.

Above, we have discussed the law-making and administrative rule-making procedures. Finally, we have to note that *courts in China often act like legislative bodies* in that they make law by issuing interpretations of laws that are binding on the courts. Every year the Supreme People's Court (SPC) issues interpretations, regulations, notices, replies, opinions, and policy statements. Most are binding on the courts; others are highly persuasive and likely to be followed. The 'interpretations' range from general statements to specific replies to inquiries from lower courts³⁵⁹, and fill in the void left by non-existent or vague laws. The main problem with this distribution of work between the NPC and the SPC is the SPC not adhering to recent process reforms to increase transparency and public participation. The SPC has started to respond to this criticism yet the questions of legislative hierarchy still remain.³⁶⁰

2.3.3 Structure of Chinese Food and Medicine Law

2.3.3.1 Foodstuffs

In China, food law is given by the NPC, the State Council, or authorities under the State Council. The Food Hygiene Law of 1995 was the fundamental food law in China. Since June 2009, the essential piece of food law has been the Food Safety Law. The Standing Committee of the National People's Congress passed the new Food Safety Law on February 28th 2009, and it came into effect at the beginning of June 2009. Based on the new law and Implementing Measures³⁶¹, Chinese food law and particularly its implementation and control will be developed. The new law uses Western terminology in promoting safety "from farm to table". Our focus in this study is primarily on the old law, as the existing law is presently more plan than practice.

The Food Hygiene Law of 1995 was basically a modern food law similar to the Codex Alimentarius model. According to the Food Hygiene Law, the administrative department of public health under the State Council shall formulate or approve and promulgate the national hygiene standards, hygiene control regulations and inspection procedures for food, food additives, the containers, packaging, utensils and equipment used for food, the detergents and disinfectants used for washing food or utensils and equipment used for food, and the tolerances for contaminants and radioactive substances in food.³⁶²

Other national food laws were based on the Food Hygiene Law. Examples of Chinese food regulations based on the former Food Hygiene Law and current Food Safety Law are:

³⁵⁸ GOV.cn Tuesday, March 11, 2008 . http://english.gov.cn/2008-03/11/content_916856.htm.

³⁵⁹ The latter means the Supreme People's Court acts similarly to the European Court of Justice, which can decide how law is to be interpreted in a case that is held by a Member State court.

³⁶⁰ Peerenboom 2008 c, 1.

³⁶¹ First Implementing Measures were published in April 2009.

³⁶² Food Hygiene Law, Article 14.

- the Novel Food Regulation
- the GMO Food Regulation
- the Health Food Regulation
- the Food Additive Regulation³⁶³.

For health foods³⁶⁴, there is a national Health Food Regulation by the Ministry of Health, which is the basic law on health foods. In addition, there are over 20 other rules or notifications by the Ministry of Health or the State Food and Drug Administration. These include the “Interim Regulations for the Registration of Health Foods”, “Provisions for Health Food Labelling”, “General Hygiene Requirements for Health Foods” and the “Notification on Preparing for Censoring Health Food Advertisements”.³⁶⁵ For clarity reasons, combining these in one piece of law might be considered in the future.

If the State has not formulated standards for a certain food, the people’s governments of the provinces, autonomous regions, or municipalities directly under the Central Government may establish *local standards* for that food and report them to the administrative department of public health under the State Council and the competent standardization administration department under the State Council for the record.³⁶⁶ The 2009 Food Safety Law upholds existing principles of legislative competence.³⁶⁷ Local standards are plentiful. In Hong Kong, for example, there is an abundance of local food law. A general food and medicine code is complemented by legislation on specific matters³⁶⁸.

According to Kan and Zhang, factors considered in formulating food standards are:

- *feasibility of standards* on the basis of research,
- current and future *risk evaluation*,
- *international* food law codes and standards of other countries, and
- *industrial* standards.³⁶⁹

When drafting new food regulations, central and regional government, businesses, associations, NGOs, and Internet are consulted³⁷⁰. With reference to better food legislation, Kan and Zhang urge that law shall be based on science, and regulators must look at the food chain from farm to table. Food law must emphasise the responsibility of food producers and sellers to guarantee food safety: food business operators must have effective in-house control, using HACCP³⁷¹ based systems. The businesses are responsible for taking dangerous products off the

³⁶³ Kan and Zhang (2002) use the term “management measures” of these pieces of law.

³⁶⁴ Health foods are foods which have a specific health function, are suitable for a certain group of people, and which are not for therapeutic purposes. Health foods will be discussed below as regards requirements on their safety and efficacy.

³⁶⁵ List of Chinese food, drug and cosmetic laws at http://www.chinafdc-law.com/laws/list_1-27_5-118_1.html.

³⁶⁶ Food Hygiene Law, Article 15.

³⁶⁷ According to Article 24 of the new law, local food laws can be developed in the absence of national laws.

³⁶⁸ Hong Kong government web page. http://www.fehd.gov.hk/safefood/foodlaw_list.html#part5.

³⁶⁹ Kan – Zhang 2002.

³⁷⁰ Kan – Zhang 2002.

³⁷¹ Hazard Analysis and Critical Control Points.

market. The government should assist by reducing over-detailed regulation and emphasizing coordination.³⁷²

The Chinese views on how to develop food law sound similar to the European approach, where food law is legally based on scientific risk analysis, global harmonization is considered important from free trade perspectives, and industry is always consulted when drafting new legislation. In China, there is not a particular authority like EFSA responsible for scientific risk assessment as regards food law. Instead, the Ministry of Health and the SFDA, which will in the near future be transferred under the Ministry, perform risk assessment.

The new Food Safety Law covers food safety evaluation, monitoring, recall and information release. In addition to passing a new Food Safety Law, the government promised to stipulate or update *more than 7,700 national standards* for the safety of foodstuffs, medicines, and other consumer goods in 2008. It is not possible to analyse the effect of this vast legislative work here. Thousands of standards mean thousands of standardised details. The government states that after the current reforms, all the requirements and testing methods should “comply with international standards”. Also a more general “National Food Safety Standard” is on the way. The national authorities shall prepare it together, and review it through a Committee³⁷³. Legislators have promised to include the general public in the process of law formulation, and to publicly post all the drafts.³⁷⁴

2.3.3.2 Medicines

The basic Chinese law on medicines is the Medicine Administration law along with its Implementing Regulations. The National People’s Congress enacted the law itself in 2001, and the State Council gave the implementing regulations in 2002. More detailed information on what is required is to be found in the “Registration Measures” given by the SFDA in 2007³⁷⁵.

Similarly to the regulation of foodstuffs, the basic laws on medicines are complemented by several pieces of administrative regulations given by the SFDA. This material could be defined as soft law as the SFDA or its predecessor, the SDA, provides it. The SFDA has an important role as a formulator of laws and administrative regulations on medicines. The regulations include rules on manufacturing licences, certification for Good Manufacturing Practice, Good Clinical Practice, Good Supply Practice, distribution, labelling and packaging, advertising, pricing, import-export, etc. Medicine marketing was in 2007 regulated in a stricter and more detailed manner because of the problems and scandals related to false advertising.

Regulations on traditional Chinese medicines have existed since 2003. Instead of safety or efficacy evaluation of traditional medicines, these Regulations are focused on general principles such as the importance of traditional medicine and its development. Also a regulation on Good Agricultural Practice of traditional Chinese medicines has existed since 2002. This regulation

³⁷² Kan – Zhang 2002.

³⁷³ See Articles 13 – 15 of the Food Safety Law Implementation Measures.

³⁷⁴ GOV.cn Saturday, March 8, 2008. http://english.gov.cn/2008-03/08/content_914117.htm.

³⁷⁵ The SFDA promulgated the latest “Measures for the Administration of Drug Registration” on July 10 2007, and they entered into force in October 1, 2007.

is interim and given by the SDA, the predecessor of the SFDA. A separate law on scientific evaluation of traditional medicines is pending, but has caused controversy.

Local government authorities have enacted their own medicine regulations, which may supplement and modify some of the national regulations. Local rules exist particularly on labelling.

2.3.4 Implementing the Law

2.3.4.1 *Pre-market Controls Used in China*

2.3.4.1.1 Foods

First of all, *enterprises and persons involved in food production and marketing must have a licence*. Enterprises engaged in food production or marketing as well as food vendors must obtain a hygiene licence issued by the administrative department of public health before they shall be permitted to apply for registration with the administrative departments of industry and commerce. No person without a hygiene licence may engage in food production or marketing.³⁷⁶ The tasks of issuance and control of hygiene licences are delegated to local officials³⁷⁷. Food safety risk assessment is “a scientific assessment performed in order to identify the possible adverse impact upon human health by biological, chemical and physical hazards of food”³⁷⁸.

The following food categories are subjected to pre-market control:

- food additives
- health foods
- novel foods
- GM foods.

Here we focus on pre-market procedures for health foods and novel foods, as these are probably the most relevant legal categories for our purposes.

Producing health foods requires an additional licence. A health food producer will have to apply to the provincial health authorities for a production permit. The permit will be attached to the manufacturer’s Hygiene Licence. As do other companies since 2002, health food manufacturers must have Good Manufacturing Practices and Hazard Analysis and Critical Control Points in place.³⁷⁹

³⁷⁶ Chinese Food Hygiene Law, Article 27. Similarly in new Food Safety Law Implementation Measures, Article 18.

³⁷⁷ Article 27.3 of the Food Hygiene Law: The measures for the issuance and control of hygiene licences shall be worked out by the administrative departments of public health of the people’s governments of the provinces, autonomous regions, or municipalities directly under the Central Government.

³⁷⁸ Food Safety Law Implementation Measures, Article 55.

³⁷⁹ Huang – Lapsley 2005, 286.

Pre-market registration of medicines and health foods is under the competence of State Food and Drug Administration (SFDA), more particularly its Department of Drug Registration.³⁸⁰ Novel foods, GMO foods, and additives are authorised by the Ministry of Health, and in the future, health foods will also be authorised by the Ministry.

All foods with health claims must undergo the approval process set forth by the SFDA. A Chinese company submits the application to provincial health administration authorities who perform preliminary examination. Upon passing this, the application is submitted to the Health Food Evaluation Centre of the State Food and Drug Administration (SFDA). *For imported foods, the application is sent straight to the SFDA.*³⁸¹

The State Food and Drug Administration, Department of Drug Registration, and the Division of Health Foods administer health foods. The tasks of the Division of Health Foods are:

- drafting criteria of marketing authorisation and research guidelines for health foods
- evaluation and approval of health foods³⁸².

The SFDA issues a Certificate of Approval on Health Food for the qualified health food, and formulates the label for the product. The Certificate can be used in connection with the label.³⁸³

Prior to submission of the application, the following reports must be obtained from an authorised laboratory:

- report of toxicology safety assessment,
- report of functionality (efficacy) evaluation,
- analytical report of active ingredient,
- report of product stability study,
- report of sanitary inspection.³⁸⁴

There are more than 30 authorised laboratories in China, although not every laboratory can conduct all tests. Each laboratory is allowed to evaluate certain claims according to its capacity. The Institute of Nutrition and Food Safety, and the Chinese Centre for Disease Control in Beijing test all imported health foods.³⁸⁵

Further regulations for the application procedure are given by a separate piece of law, the Regulation on Application and Acceptation of Health Food of Ministry of Public Health

³⁸⁰ According to the SFDA's web page, the tasks of SFDA's Department of Drug Registration are, among others,

- to draft and revise national drug standards,
- to control approval and registering of new drugs, drugs with national standards, and imported drugs,
- to implement protection system for traditional Chinese medicines,
- to draft criteria of marketing authorisation for health food, and
- to control approval of health foods. <http://www.sfda.gov.cn/cmsweb/webportal/W44993641/index.html>.

³⁸¹ The Measures for the Administration of Health Food Registration, which took effect July 2005. Huang – Lapsley 2005, 264-265.

³⁸² SFDA web page. <http://www.sfda.gov.cn/cmsweb/webportal/W44993701/index.html>.

³⁸³ Article 5.

³⁸⁴ Huang – Lapsley 2005, 276-282.

³⁸⁵ Huang – Lapsley 2005, 282.

(1999). Article 6 of the Regulation lists the necessary documents and samples for domestically produced and imported health foods respectively. In addition to the above-mentioned research reports, and three product samples, the following information must be included in the application for Imported Health Food:

1. Hygiene Permit Application Form for Imported Health Foods
2. Product formulation and its relevant scientific evidence
3. Name and content of active ingredient(s) and the analytical procedure for the ingredients
4. Processing techniques and flowchart
5. Product quality specification (industry standard)
6. Inspection reports (as stated previously) by the authorised laboratory
7. Product packaging design (including product label)
8. Product manual or description
9. An entrust contract, is an applicant is an trustee³⁸⁶
10. Evidence documents such as product sale permit issued by relevant authority from the manufacturer's country
11. Other relevant data in support of the approval process.³⁸⁷

The SFDA will evaluate the application with respect to the following aspects:

- Health food name: whether it is accurate and scientifically sound.
- The application: whether it is complete, translated into Chinese, and legible.
- Formulation: which are the raw materials used.
- Manufacturing technique: whether good manufacturing practice is followed.
- Quality: what is the process for controlling active ingredients.
- Safety: evaluating the toxicological test reports.
- Efficacy: evaluating the functionality assessment reports.
- Active ingredient: evaluating the analytical report of the active ingredient.
- Product stability: whether the product will last two years of shelf life.
- Hygiene: evaluating the hygiene reports.
- Label and manual: whether they are accurate and true.³⁸⁸

If the SFDA approves the health food, it issues an “Approval Certificate of Health Food” or “Approval Certificate for Imported Health Food”. Together with the certificate, the product receives a serial number such as Foodstuff/Health 2007 No1234. while simultaneously receiving the right to use the health food symbol. Both the serial number and the symbol must be marked on health food packaging.³⁸⁹ For imported foods, the Certificate is inspected by the food hygiene and inspection agency at a Chinese entry port³⁹⁰.

³⁸⁶ An entrusted agent of a foreign functional food manufacturer.

³⁸⁷ Health Food Regulation, Article 6. Huang – Lapsley 2005, 282.

³⁸⁸ Huang – Lapsley 2005, 284-285.

³⁸⁹ Huang – Lapsley 2005, 265.

³⁹⁰ Huang – Lapsley 2005, 286.

The pre-market control is not solely a responsibility of the control authorities. Also *the food industry operators themselves* are responsible for finding and controlling risks in their activities. According to the Chinese Food Hygiene Law³⁹¹, “Enterprises engaged in food production or marketing shall improve their own system for food hygiene control, appoint full-time or part-time workers to control food hygiene and strengthen inspection of the foods they produce or market”. It is further stated³⁹² that food and food additives³⁹³ may be dispatched from factory or sold only after their producers have carried out inspection and found them to meet the principles according to the hygiene standards and the hygiene control regulations.

In China, the plan is to further enhance self-discipline of food industry enterprises by creating and enforcing a culture of credibility. The New Food Safety Law and its Implementation Measures further strengthen the principle of self-control. Enterprises are the first responsible parties for food safety. Blacklists of operators are created, and supervision efforts are focused on the most susceptible enterprises according to risk management principles.³⁹⁴ This focus on self-discipline and supervision based on different risk categories is similar to the European approach. If companies themselves were responsible, the authorities would save in supervision costs.

The first Novel Food Regulation in China was issued in 1990. In 2007, a new Regulation³⁹⁵ was issued and came into force at the beginning of December 2007. To drive the novel food industry, the new regulation aims to remove complex approval procedures, while tightening food safety measures.³⁹⁶ The government wants to encourage scientific research and development of novel foods³⁹⁷ and to add greater variety to the market.

The aim of the Novel Food Regulation is to strengthen supervision and administration of novel foods, and to safeguard the health of consumers.³⁹⁸ The Novel Food Regulation was based on the Food Hygiene Law³⁹⁹ of the People’s Republic of China. Novel foods are subject to pre-market approval by the Ministry of Health. It is prohibited to manufacture or use as food or food raw materials, materials corresponding to the definition of novel foods in Article 2 of the Novel Food Regulation, if they have not yet been approved and published as novel foods by the Ministry of Health⁴⁰⁰.

According to Article 23 of the Novel Food Regulation, “Enterprises manufacturing, operating and/or using novel foods *shall not claim or imply the therapeutic effects and health*

³⁹¹ Article 18.

³⁹² Article 24

³⁹³ And also food contact materials.

³⁹⁴ Five-Year Plan for Food and Drug Safety. April 2007. Page 9.

³⁹⁵ Ministry of Health: Administrative Measures on Novel Foods.

³⁹⁶ The Ministry of Health according to Chinadaily.com.

³⁹⁷ Novel Food Regulation, Article 4.

³⁹⁸ Novel Food Regulation, Article 1.

³⁹⁹ In the Food Hygiene Law, it is stated: “Before beginning production of new types of foods or food additives using new resources, the enterprises engaged in their production or marketing must submit the data necessary for the evaluation of the hygiene and nutrition of such products;.... Before beginning production of the above new products, it shall also be necessary to provide samples of the products for examination and approval, in accordance with the specified procedures for examining and approving food hygiene standards.” Article 20.

⁴⁰⁰ Novel Food Regulation, Article 18.

functions of the novel food.” If a product is a novel food and health claims are wanted, the health food procedure applies, in which case safety and efficacy are both evaluated by the SFDA. Novel food assessment is safety assessment, and does not include efficacy assessment.

An application for a novel food at the Ministry of Health shall include the following materials:

- (1) Application for hygiene administration permit for novel food;
- (2) Research and production report;
- (3) Brief summary and flow chart of processing techniques;
- (4) Product quality standards;
- (5) Status on research and production at home and abroad, as well as safety related documents;
- (6) Product label and instructions; and
- (7) Other materials helpful to assessment and review.

In addition to these documents, a sealed product sample or 30-grams of raw material is required. In the case of imported novel food, it is also required to submit certificates by food control authorities indicating that the food is considered legal in the exporting country.⁴⁰¹

After accepting applications for novel foods, the Ministry of Health organises the *Assessment Committee* to conduct a preliminary technical examination. In case additional or corrective materials are needed, the applicant shall cooperate. After the preliminary technical examination, the Assessment Committee shall determine the safety test items, test sample batches, test methods and testing institutions of the novel food, and decide on whether to conduct on-site examination and collect and seal samples, and inform the applicant. Generally, testing institutions accredited by the Ministry of Health shall carry out the safety tests. In case on-site examination and collection of sealed samples is required, the applicants of domestically-produced novel foods shall file an application to the local health administration department at the provincial level which shall organise implementation of such on-site examination, collection and sealing of samples. Applicants of imported novel foods shall file the applications to the Ministry of Health, who organise the implementation (of the on-site examination, collection and sealing-up of samples).⁴⁰²

2.3.4.1.2 Medicines

As with the European system, China also has pre-market control over the dominant regulatory mechanisms for medicines. Registration of medicines is under the responsibility of the SFDA. Part of its powers has been delegated to local level government authorities (provinces, autonomous regions or municipalities directly under the central government). These local level authorities can issue manufacturing licenses and approve medicine advertisements⁴⁰³.

Good Manufacturing Practice (GMP) is where medicine safety begins. GMP is a system to ensure products are consistently produced and controlled according to quality standards.

⁴⁰¹ Novel Food Regulation Article 11.

⁴⁰² Novel Food Regulation, Article 12.

⁴⁰³ Tsoi 2007.

It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. A directive circular issued by the Ministry of Health in July 1995 marked the official launch of GMP certification in China. The China Certification Committee for Drugs (CCCD) was established in the same year.⁴⁰⁴

The Chinese pre-market control of medicinal products is based on one authorisation procedure, the result of which applies to the whole country. It is stated in the law that local people's governments and officials shall not restrict or exclude the entrance of authorised pharmaceuticals under the justification of conducting inspections⁴⁰⁵. The goal is to harmonise medicine law in China and to remove local barriers to trade.

The SFDA is responsible for pre-market approval of medicines. There are five divisions and one office under its Department of Drug Registration, including:

- Division of *Traditional Chinese Medicine*
- Division of *Pharmaceuticals*
- Division of *Biological Products*
- Division of Health Food
- Division of General Management
- Office for Acceptance of Drug Application.⁴⁰⁶

The Department of Drug Registration, Division of Traditional Chinese Medicine has the following tasks:

- to draft national standards and research guidelines for traditional Chinese medicines, Chinese crude drugs and prepared slices thereof, and natural medicines;
- *to evaluate and approve new drugs*, drugs with national standards and import products of traditional Chinese medicine preparations, prepared slices of Chinese crude drugs, Chinese crude drugs and natural medicines;
- to evaluate and approve clinical trials of traditional Chinese medicines;
- to approve protected traditional Chinese medicinal products.

The Department of Drug Registration, Division of Pharmaceuticals has the following tasks, among others,

- to draft national standards and research guidelines of pharmaceuticals;
- *to evaluate and approve new drugs*, drugs with national standards and import drugs;
- to evaluate and approve clinical trials of new drugs.

All *new medicines* must be registered according to the Registration measures. The registration process has *three steps*: pre-clinical studies, clinical studies, and approval. First, the applicant himself conducts the pre-clinical studies. In order to conduct clinical studies, one must apply to the provincial authorities with the results of the pre-clinical studies. The provincial authorities examine the medicine with assistance from state-sponsored laboratories, and submit their

⁴⁰⁴ Wikipedia. http://en.wikipedia.org/wiki/Pharmaceutical_industry_in_China.

⁴⁰⁵ Medicine Administration Law, Article 69.

⁴⁰⁶ SFDA web page. <http://www.sfda.gov.cn/cmsweb/webportal/W44993641/index.html>.

findings to the SFDA. The SFDA conducts further technical tests and decides whether clinical tests will be allowed. If approved, the applicant conducts the clinical studies. The results from these studies, accompanied by product samples, will then be sent to provincial authorities for manufacture approval. The decision of the provincial authorities⁴⁰⁷ is subjected to final clearance by the SFDA. If approved by the SFDA, the applicant will receive a *Certificate of New Medicine* and a *Production Approval Number*.⁴⁰⁸

Generic medicines do not require clinical studies unless they are solid oral medicines. In order to register for manufacture approval, the applicant must submit pre-clinical studies and product samples to provincial authorities. The decision of the provincial authorities is subject to final clearance by the SFDA.⁴⁰⁹

Imported medicines, referring to medicines that are not manufactured in China, must already have obtained market approval in the country where they are manufactured. In addition, they must undergo clinical testing and be registered in China similarly to new medicines. If the medicine does not have a Product License in the originating country, it may still be imported if there is a clinical need in China for the medicine in question, and safety and efficacy are confirmed by independent trials. Imported medicines receive a *Pharmaceutical Import Registration Certificate*.⁴¹⁰

According to Article 8 of the Medicine Administration Law, to establish a pharmaceutical producing enterprise, the following requirements must be met:

- (1) It shall be staffed with legally certified pharmaceutical technical personnel, engineering technical personnel, as well as corresponding skilled workers.
- (2) It shall have factory premises, facilities and a sanitary environment suitable for the medicines produced.
- (3) It shall have a unit or competent personnel capable of inspecting the quality of the medicines produced, as well as necessary instruments and equipment.
- (4) It shall have rules and regulations to ensure the quality of medicines.

Besides manufacturing, *distribution* of medicines is under strict control. The Chinese are striving to erode the serious problems related to counterfeit or fake medicines. A *Pharmaceutical Trade License* is required for wholesale or retail⁴¹¹ trade of pharmaceuticals. Pharmacies or hospitals may also prepare medicinal preparations, provided that they have a *Dispensing Permit for Medical Organisations*⁴¹². Medicinal preparations made by medical organisations may not be sold on the market⁴¹³.

⁴⁰⁷ The production license is issued by the pharmaceutical supervisory and administrative department of the province, autonomous region, or municipality directly under the Central government in which the enterprise is located. Medicine Administration Law, Article 7.

⁴⁰⁸ Medicine Administration Law, Article 31. Tsoi 2007.

⁴⁰⁹ Tsoi 2007.

⁴¹⁰ Medicine Administration Law, Article 39. Tsoi 2007.

⁴¹¹ Medicine Administration Law, Article 14.

⁴¹² The permit is issued by the pharmaceutical supervisory and administrative departments of the provinces, autonomous regions or municipalities directly under the central government. Medicine Administration Law, Article 23.

⁴¹³ Medicine Administration Law, Article 25.

According to the Medicine Administration Law, Article 15, to establish a pharmaceutical trading enterprise, the following requirements must be met:

- (1) It shall be staffed with legally certified pharmaceutical technical personnel.
- (2) It shall have business premises, equipment, storage facilities and a sanitary environment suitable for the pharmaceuticals in which it trades.
- (3) It shall have a quality control agent or personnel suitable for the pharmaceuticals in which it trades.
- (4) It shall have rules and regulations to ensure the quality of the pharmaceuticals in which it trades.

Distribution, retail and trading of medicines are subject to more specific criteria given in the Opinion on Strengthening Supervision of Pharmaceuticals and Promoting the Development of a Modern Logistics for Pharmaceuticals. The Opinions provide rules on medicine supply, purchase, inspection, storage, etc.⁴¹⁴

Hospitals and clinics practicing *traditional Chinese medicine* must undergo examination and be licensed as a medical institution. Practitioners of traditional medicine are required to pass a qualifying examination and obtain a license through registration.⁴¹⁵

Medicinal product *advertising* is also under pre-market control. All advertisements have to be pre-approved by provincial medicine control authorities. This applies to all pharmaceutical advertisements, published through radio, cinematography film, television, newspaper, magazine, periodical and other media. An advertiser shall, when applying for advertisement examination, submit relevant documentation to the officials of the place where the enterprise is located⁴¹⁶. The officials must examine and inspect, prior to publication, the contents of advertisements in accordance with the law. Only advertisements which are examined, approved and given a pharmaceutical advertising registration number may be published.⁴¹⁷

According to Access China Management Consulting Ltd., the Chinese process of application and approval for imported medicine registration is “very complex”. They claim that Chinese pharmaceutical authorities administer and control the process by various and variable administrative measures and regulations with lack of transparency. However, they believe that the ongoing consolidation of the regulations will eventually contribute to a healthier market environment.⁴¹⁸ Proprietary data is often submitted as part of a medicine registration application, and some companies have been reluctant to send such sensitive information to China out of concern that their intellectual property might be compromised. According to the US-China Business Council, there has been progress in protecting proprietary data from unfair commercial use.⁴¹⁹

⁴¹⁴ Tsoi 2007.

⁴¹⁵ Chinese Regulations on Traditional Chinese Medicines. Chapter II.

⁴¹⁶ The pharmaceutical supervisory and administrative departments of the provinces, autonomous regions, or municipalities directly under the central government. Medicine Administration Law, Article 60.

⁴¹⁷ Advertising law, Article 34. Medicine Administration Law, Article 60.

⁴¹⁸ Access China 2007.

⁴¹⁹ US-China Business Council 2008.

2.3.4.2 Post Market Controls in China

2.3.4.2.1 Foods

The Food Hygiene Law aimed to ensure the supervision system of national food hygiene: the central and regional health executive departments bear the responsibility of supervision⁴²⁰. According to Article 17, the departments in charge of control of food production or marketing of the people's governments at various levels shall *strengthen control* of food hygiene and *oversee the implementation* of the Food Hygiene Law. Supervision of food production and marketing is under the responsibility of administrative departments of industry and commerce and the administrative departments of public health⁴²¹.

The new Food Safety Law Implementation Measures contain similar phrases: Local people's governments shall "reinforce food safety supervision"⁴²². Local health authorities shall coordinate the work of various food-related authorities and develop local food safety risk monitoring programs⁴²³. The safety monitoring work itself, such as collecting and analysing samples, shall be done by "technical institutions"⁴²⁴.

Article 33 of the Chinese Food Hygiene Law listed the functions of food hygiene supervision reasonably precisely:

- (1) to provide monitoring of, inspection of and technical guidance for food hygiene;
- (2) to contribute to the training of personnel for food production and marketing and to supervise the medical examinations of such personnel;
- (3) to spread knowledge of food hygiene and nutrition, provide appraisals of food hygiene and publicise the existing condition of food hygiene;
- (4) to conduct hygiene inspections of sites and designs for the construction, extension or renovation of enterprises engaged in food production or marketing and participate in the inspection and acceptance of finished projects;
- (5) to investigate accidents involving food poisoning or food contamination and take appropriate measures of control;
- (6) to make rounds of inspection and supervision concerning acts in violation of this Law;
- (7) to determine the responsibility of persons who violate this Law and *impose administrative penalties* on them according to law; and
- (8) to take charge of other matters that concern food hygiene supervision."

According to the Food Hygiene Law, the health authorities of the people's governments at county level or above shall appoint food hygiene supervisors. The supervisors shall be *qualified specialists* certified by the health authorities at the corresponding level. Food hygiene supervisors shall carry out the tasks assigned to them by the administrative departments for health. It was also interestingly stated in the Food Hygiene Law that "food hygiene supervisors must enforce laws impartially, be devoted to their duties and shall not take advantage of their positions for their own

⁴²⁰ Kan – Zhang 2002.

⁴²¹ Food Hygiene Law, Article 29.

⁴²² Food Safety Law Implementation Measures, Article 2.

⁴²³ Food Safety Law Implementation Measures, Article 5.

⁴²⁴ Food Safety Law Implementation Measures, Article 9.

benefit".⁴²⁵ The law enforcement department has the right to adopt *executive controlling measures*. While carrying out their tasks, food hygiene supervisors may obtain information from the producers or marketers of food, request any necessary data, enter the production or marketing premises for the purposes of inspection, and obtain free samples in accordance with regulations. The producers or marketers of food may not turn down such requests nor hold back any information. The food hygiene supervisors shall be obliged to keep confidential any technical data provided by the producers or marketers.⁴²⁶ The local health authorities may take provisional measures of control towards a producer or marketer of food who is responsible for a food poisoning accident which has already occurred or for which there is evidence of the possibility of it occurring. They can seal up the food and its raw materials. Food proven to be contaminated should be destroyed.⁴²⁷

The Novel Food Regulation refers to the supervision articles of the Food Hygiene Law. It states that local authorities shall conduct supervision and inspections on novel foods according to the Food Hygiene Law⁴²⁸. The Ministry of Health shall regularly gather food safety information about novel foods, make timely announcements to the public, and, if necessary, issue early warnings or reassess the novel food that has food safety problems⁴²⁹. The Health Food Regulation similarly refers to the Food Hygiene Law and its post-market control mechanisms. As the Food Safety Law has replaced the Food Hygiene Law, the control mechanisms of the Food Safety Law currently apply. The Ministry of Health and the current authority responsible for health food approvals, the SFDA, have approved thousands of health foods, and their supervision is becoming more complicated⁴³⁰.

2.3.4.2.2 Medicines

Post-market control of medicines is under the competence of the SFDA and the local (provincial, municipal etc.) authorities. In order to discover any illegal activities, government officials shall organise investigations on medicines, which have been approved for production or import. They are authorised to conduct *supervision and inspections* over the research, development, production and trade of approved medicines, as well as the medical organisations' use of medicines. The units and individuals concerned shall not refuse to comply. Supervisory and administrative officials shall present certificate documents while conducting supervision and inspection, and shall not divulge technological and business secrets.⁴³¹ Also sampling examinations on the quality of medicines may be conducted⁴³². The authorities may take administrative coercive measures including sequestration and banning against pharmaceuticals and other relevant materials, which have been proven to be of possible harm to people's health.

Production or import *licences shall be revoked* if it is discovered that:

⁴²⁵ Articles 24 and 35 of the Chinese Food Hygiene Law.

⁴²⁶ Article 35.

⁴²⁷ Article 37.

⁴²⁸ Novel Food Regulation, Article 24.

⁴²⁹ Novel Food Regulation, Article 25

⁴³⁰ Huang – Lapsley 2005, 263.

⁴³¹ Medicine Administration Law, Article 64.

⁴³² Medicine Administration Law, Article 65.

- curative effects of the medicine are uncertain or poor,
- the medicine produces serious adverse reactions, or
- for other reasons the medicine is harmful to people’s health.

The medicines whose licenses have been revoked shall not be allowed to be produced, imported, sold or used. Those, which have already been produced or imported, shall be destroyed or disposed of under the supervision of the authorities.⁴³³

Pharmacovigilance activities are under the shared responsibility of operators and the State. A reporting system over any adverse reactions of pharmaceuticals shall be practiced by the State. Medicine manufacturers, traders, and medical institutions shall conduct regular surveys on the quality, curative effects and adverse reactions of the pharmaceuticals they have produced, traded or used. When serious adverse reactions possibly related to the use of the medicines are discovered, they must be promptly reported to the local medicine control authorities and the local health authorities, which will formulate detailed measures to be taken. These measures include cessation of production, sale, and use of the medicine.⁴³⁴

2.3.4.3 Penalties Used in China

2.3.4.3.1 Foods

In China, the court system has traditionally not been separated from administration. Cases have been handled as police or administrative issues.⁴³⁵ This remains the case with foodstuff and medicine administration. The administrators are entitled to carry out various *executive punishments* stipulated in the Food Safety Law.

In the former Food Hygiene Law, there were separate penalty regulations for:

- whoever causes a food poisoning accident,
- whoever causes a serious food poisoning accident,
- whoever produces or markets foods without a hygiene licence,
- whoever fails to comply with hygiene requirements,
- whoever produces or markets food of which the production or marketing has been prohibited,
- whoever produces or markets infant or children’s food not conforming to nutrition and hygiene standards,
- whoever produces, markets or uses food additives, food contact materials, or disinfectants not conforming to hygiene standards,
- whoever produces or markets *a health food without authorisation*, or presents *fraudulent health claims*,
- whoever fails to comply with the labelling requirements,
- whoever works without a personal health certificate or uses sick personnel.

⁴³³ Medicine Administration Law, Article 42.

⁴³⁴ Medicine Administration Law, Article 71.

⁴³⁵ Huotari – Seppälä 2005, 131.

For every breach, withdrawal of contaminated products, confiscation of illegal gains, fines, and revocation of licence are possible. The yuan amounts for fines set in the Food Hygiene Law, range from 1,000 to 50,000 yuan, were thus fairly low for large companies, but significant for smaller companies. In the new Food Safety Law, the yuan amounts changed. Currently, fines range from 2,000 yuan to ten times the value of the commodity in question. This means there are no maximum fine amounts for crimes affecting large volumes of foods. The health authorities of the local people's governments determine the administrative penalties. The administrative penalty decision may be appealed to the higher health authority⁴³⁶, or to a people's court⁴³⁷. If someone does not appeal but neither complies with the decision, the decision can be enforced by a court⁴³⁸.

Punishments are not regulated separately in the Novel Food Regulation or the Health Food Regulation. Instead, they refer to punishments stipulated by the Food Hygiene Law, which has been replaced by the Food Safety Law. For example, manufacturing or operating novel food that is not approved by the Ministry of Health, or using novel food that is not approved by the Ministry of Health as a raw material for food processing, the enterprise was to be penalised by the health administrative department of the people's government at county level or above in accordance with Article 42 of the Food Hygiene Law⁴³⁹. If food was produced under the name of health food when it has not been accepted according to the Health Food Regulation, penalties listed in Article 45 of the Food Hygiene Law apply⁴⁴⁰.

In addition to administrative penalties, violating food laws may lead to *civil responsibility*. This means that if someone causes food poisoning or transmission of disease, he must compensate for personal and financial damage.⁴⁴¹ Disputes are resolved in mediation, arbitration, and courts. The courts do not have adequate powers to enforce judgments, and coercive means are not preferred in civil cases. Enforcement of judgments is thus uncertain and depends on the local financial interest and relationships of the enforcement authorities to banks that are capable of seizing wages.⁴⁴²

For causing a serious food poisoning accident or putting poisonous raw materials in foods, *criminal responsibility* is also possible⁴⁴³. If health authorities abuse their authority and neglect their duties, disciplinary sanctions follow. Accepting bribes or causing a serious accident may also lead to criminal responsibility of the health authority officer⁴⁴⁴. Violating or threatening

⁴³⁶ This is called applying for consideration. Ultimately, administrative penalties may be appealed to the SFDA. According to the SFDA web page, its Department of Policy and Regulation, Division of Law Enforcement Supervision has the following tasks:

- “administrative activities supervision, hearing, administrative reconsideration, response to lawsuit and compensation;
- guidance on legal construction and law popularisation and publicising within the food and drug administration system”.

⁴³⁷ Article 50.1.

⁴³⁸ Article 50.3.

⁴³⁹ Novel Food Regulation, Article 26.

⁴⁴⁰ Health Food Regulation, Article 29.

⁴⁴¹ Food Hygiene Law, Article 48.

⁴⁴² Seppänen 2005, 594.

⁴⁴³ Food Hygiene Law, Article 39.2.

⁴⁴⁴ Food Hygiene Law, Articles 51 and 52.

health authorities leads to criminal responsibility. Otherwise obstructing officials will lead to an administrative penalty for disrupting public security⁴⁴⁵.

Civil and criminal cases are handled by people's courts on various levels. Administrative enforcement agencies are not willing to hand over their cases for criminal prosecution, because administrative penalties enhance their own operating budgets⁴⁴⁶. The autonomy of courts and the enforcement of judgments are by many scholars considered as problematic in China⁴⁴⁷. The judicial system as a whole is weak and under the control of the Communist Party⁴⁴⁸. Independence of the judiciary relates to the more general concept of rule of law discussed above.

2.3.4.3.2 Medicines

Chapter IX of the Medicine Administration Law addresses Legal Responsibility, i.e. penalties. The Regulations on traditional Chinese medicine also include details on offences and sanctions.⁴⁴⁹ There are different types of penalty for different types of breaches of the Medicine Administration Law. There are separate penalty regulations for those who:

- produce or trade in medicines without obtaining a Pharmaceutical Production Licence, Pharmaceutical Trade License, or Dispensing Permit of Medical Organisations⁴⁵⁰,

⁴⁴⁵ Food Hygiene Law, Article 53.

⁴⁴⁶ Mertha 2008, 2.

⁴⁴⁷ See Seppänen 2005 on how empirical evidence is missing on these issues.

⁴⁴⁸ Mertha 2008, 2.

⁴⁴⁹ Chapter V.

⁴⁵⁰ “Those who *produce or trade in medicines without obtaining a Pharmaceutical Production Licence, Pharmaceutical Trade Licence, or Dispensing Permit of Medical Organisations*, shall be placed under ban, have the unlawfully produced and sold medicines and any unlawful income confiscated, and may concurrently be fined a sum of money more than two but less than five times the value of the medicines unlawfully made or sold.” Article 73.

- produce and sell fake medicines⁴⁵¹ or medicines of inferior quality^{452, 453},
- do not comply with the quality control standards for production, trade and research⁴⁵⁴,
- purchase medicines from enterprises without the Pharmaceutical Production Licence or Pharmaceutical Trade Licence⁴⁵⁵,
- import pharmaceuticals and fail to register at the port⁴⁵⁶,
- forge, alter, trade, lease or lend licences or pharmaceutical approval certificates⁴⁵⁷,
- provide false certificates or samples or receive a licence by cheating⁴⁵⁸,
- trade in pharmaceuticals and fail to keep purchase records⁴⁵⁹,
- sell medicines with incomplete label information⁴⁶⁰,
- give or receive commissions in secret or property interests to/from other enterprises or physicians during purchase or sale of pharmaceuticals⁴⁶¹,

⁴⁵¹ “Those who *produce and sell fake medicines* shall have his unlawfully produced or sold medicines and any unlawful income confiscated, and concurrently be fined a sum of money more than two but less than five times the value of the medicines unlawfully produced and sold. Those who have an approval certificate of pharmaceuticals shall have the certificate revoked, and be ordered to suspend production or business operations pending rectification; if the circumstances are serious, the party shall have Pharmaceutical Production Licence, or Pharmaceutical Trade Licence or Dispensing Permit of Medical Organisations revoked.” Article 74.

⁴⁵² “Those who *produce and sell medicines of inferior quality* shall have his unlawfully made and sold medicines and any unlawful income confiscated, and be concurrently fined the sum of money more than two but less than three times the value of the medicines unlawfully made or sold; if the circumstances are serious, the party shall be ordered to suspend production or business pending rectification, or have the pharmaceutical approval certificate revoked and his Pharmaceutical Production Licence, or Pharmaceutical Trade Licence or Dispensing Permit of Medical Organisations revoked.” Article 75.

⁴⁵³ “The person-in-charge or personnel directly liable in the enterprise or other unit which produces and sells fake medicines or produces and sells pharmaceuticals of inferior quality shall not be permitted to engage in the production and trade of pharmaceuticals for *ten years*, if the circumstances are serious. The producers’ supplementary materials, packaging materials and production equipment which are used exclusively for producing fake medicines and medicines of inferior quality shall be confiscated.” Article 76. “Those who provide facilities including transportation, preservation and storage that have been or should have been aware of the fakery or inferior quality of the pharmaceuticals, shall have the entirety of his income from such transportation, preservation and storage confiscated, and concurrently be fined a sum of money more than 50% but less than three times the value of the unlawful income. Those whose acts constitute a crime shall be investigated for criminal liabilities.” Article 77.

⁴⁵⁴ “Pharmaceutical producing enterprises, trading enterprises, pharmaceutical non-clinical safety appraisal research institution, and pharmaceutical clinical testing institutions, shall be served a warning and be ordered to amend themselves within a prescribed time limit if they do not carry out the stipulations of the “Quality Control Standard of Pharmaceutical Production,” the “Quality Control Standard of Pharmaceutical Trade,” the quality control standard of pharmaceutical non-clinical research, and the quality control standard of pharmaceutical clinical testing. Those who do not rectify their mistakes within the prescribed time limit shall be ordered to suspend production and business operations pending rectification, and be concurrently fined more than 5000 but less than 20,000 RMB. If the circumstances are serious, they shall have their Pharmaceutical Production Licence, Pharmaceutical Trading Licence or Dispensing Permit of Medical Organisations revoked.” Article 79.

⁴⁵⁵ Article 80.

⁴⁵⁶ Article 81.

⁴⁵⁷ Article 82.

⁴⁵⁸ Article 83.

⁴⁵⁹ Article 85.

⁴⁶⁰ Article 86.

⁴⁶¹ Article 90 and 91.

- act against regulations on pharmaceutical advertising⁴⁶²,
- are supervisors and issue certificates or licences without grounds⁴⁶³, or neglect their supervisory duties⁴⁶⁴, or collect illegal fees⁴⁶⁵,
- are inspections agencies and produce false inspection reports⁴⁶⁶,
- are supervisors or inspectors and participate in production or trade of pharmaceuticals⁴⁶⁷.

The administrative penalties include revocation of licences, personal ban to engage in pharmaceutical business, confiscation of illegal gains, and fines. The amount of the fine depends on the volumes of the illegal business. The decision to impose administrative sanctions is made by the pharmaceutical supervisory and administrative departments at or above the county level. The original approval departments shall decide on revocation of licences.⁴⁶⁸ There is a possibility of appeal to the SFDA.

To ensure the marketers take the rules on medicine advertising seriously, the Chinese government has made post-market control methods and punishments more severe. Advertisements with illegal content will be revoked of all advertising approval numbers, and *application for advertising approval for the medicine in question will be banned for a year*. In the case of illegal advertisements gravely deceiving and/or misleading consumers by exaggerating the scope of applicability and effects of the medicine, the medicine will be *suspended from sale* and the marketer ordered to dispel the negative impact of the illegal advertising.⁴⁶⁹

Civil responsibility towards patient consumers is referred to in Article 93 of the Medicine Administration Law: “If pharmaceutical-producing enterprises, trading enterprises or medical organisations act against this law which results in damages to the users of pharmaceuticals, they shall bear liabilities of compensation in conformity with relevant regulations.” Chinese law does not require negligence of fault of a manufacturer to give rise to product liability. This means manufacturers are liable if any casual links between a defective pharmaceutical and a loss of a victim are found. Lawyers recommend product liability insurance for manufacturers.⁴⁷⁰

Criminal responsibility is also relevant for several types of breach of the Medicine Administration Law. For example production or sale of unauthorised, false or inferior quality pharmaceuticals⁴⁷¹, production of false inspection reports⁴⁷², and misuse of authority⁴⁷³ may constitute crimes.

⁴⁶² Article 92.

⁴⁶³ Article 94.

⁴⁶⁴ Article 97.

⁴⁶⁵ Article 96.

⁴⁶⁶ Article 87.

⁴⁶⁷ Article 95.

⁴⁶⁸ Article 88.

⁴⁶⁹ Hong Kong Trade Development Council web page. <http://www.tdctrade.com/alert/cba-e0705g.htm>.

⁴⁷⁰ Tsoi 2007.

⁴⁷¹ Articles 73, 74 and 75.

⁴⁷² Article 87.

⁴⁷³ Article 99.

2.3.5 NGO Regulation and Self-Regulation

The Chinese government is calling for the participation of consumers, NGOs⁴⁷⁴, and food companies in establishing food safety standards. In a document submitted to the World Health Organization in 2002, China called for increased participation on the part of “consumers, food industry and other stakeholders”. China has focused on increasing consumer awareness by hosting an annual “Food Hygiene Law Education Week” and implementing other educational programs on the importance of sanitary food handling.⁴⁷⁵ This way some of the responsibility can be shifted onto consumers themselves, and the large numbers of food poisoning incidents they cause can be lowered.

The civilian consumer protection group system also plays an important role in Chinese food regulation. Consumer groups, such as the Chinese Consumer Association, obtain licenses from local government authorities to independently regulate and inspect food production facilities and plants. They also hear complaints and comments from consumers and report back to local government officials.⁴⁷⁶ These groups are important in protecting people’s rights. In addition, self-regulation by the industry exists: various chambers of commerce recommend their own voluntary standards to food producers. These standards cover many areas of food production. Increasingly food producers are adopting voluntary standards in order to achieve better market success.⁴⁷⁷

The new Food Safety Law urges both the industry organisations and social groups to be more involved. According to Article 7, *food industry organisations* shall tighten industry self-discipline, and guide producers and traders in complying with the law. In Article 8, the state encourages *social and community groups* to conduct educational activities concerning food safety laws. Article 8 also urges the *media* to publicise laws for free, and to monitor acts that violate the law. It is interesting that media is also given responsibility on food safety. There seems to be a trend of shared responsibility that can additionally be noted in the European and American discussions on who is responsible for obesity.

Voluntary approaches have been criticised for not being enough, and greater government involvement has been demanded. China must build the capacity to oversee food production within its borders. Several severe food safety scandals have been the result of unsafe or inferior ingredients in processed foods, or chemical and pesticide residues.⁴⁷⁸ These problems cannot be resolved through self-regulation or consumer awareness only. Food safety must also be a priority of the government, not simply of consumers, their organisations, and the food industry.

⁴⁷⁴ The term “NGO”, non-governmental organisation, means organisations outside of state systems, including advocacy organisations, non-profit service-providing institutions, religious groups, and social welfare organisations. Ma, 2002.

⁴⁷⁵ Li 2005, 30.

⁴⁷⁶ Li 2005, 30-31.

⁴⁷⁷ Bian 2004

⁴⁷⁸ Li 2005, 30.

2.4 Legal Foundations: Comments

In this chapter, we have discussed the mechanisms in which food and medicine laws are made and implemented in the EU and China, without yet examining substantial rules on safety, efficacy, and marketing of medicines. Here we comment on some of these general legal issues.

2.4.1 Pluralism in Sources of Law

A pluralist view of law does not focus on the nation state as the only source of all law. It is acknowledged that the sources of law are varied, and may also be found in:

- the interaction of states (international law such as WTO and Codex; EU law),
- localities within the nation state (local or provincial regulation; state law in federal systems),
- shared or collective projects (the internal regulation of corporations; professional self-regulation; contracts), and
- religious communities or organisations (for example Torah; canon law; Islamic law), or minority ethnic groups (traditional law and custom).⁴⁷⁹

A food company or a medicine company can be seen as part of local, national, and global networks of communities created through laws and contracts. Above, we have discussed hard law, administrative soft law, and self-regulation on various levels. Also, religious rules and traditional customs affect the use of foods and medicines. For example, kosher rules could be seen as soft law, as kosher certificates resemble environmental or fair-trade certificates. We will not go further into religious rules, even though they are sometimes relevant for developers of functional foods.⁴⁸⁰

Cotterrell links law with *community*. In a law-and-community perspective, responsibility is the individual's obligation to maintain mutual trust in the community in question. Individuals are usually involved simultaneously in many different communities, where responsibility is formed and judged. Communities are heterogeneous and potentially conflicting. Liability depends on what a reasonable member of a community is expected to know. In practice, the most powerful regulation wins.⁴⁸¹ Even though nation states do not produce all the law, they are in our opinion still the most important decision-makers. Nation states decide whether or not to be part of international agreements, whether or not to delegate legislative power at local level, whether or not to tender factual legislative competence to administrative organs, and whether or not to leave room for self-regulation and give binding effect to it. The decision of how to regulate (on what level, through which instrument, etc.) needs to be a conscious one.

⁴⁷⁹ Cotterrell 2006, 161-162.

⁴⁸⁰ For example: Kosher means pure food by Jewish law. Animals need to be slaughtered in that fashion. Islamic people will not eat blood, alcohol, or pork meat. Blood is also avoided by certain Christian movements. The Orthodox Christian will not eat meat during Lent, the Catholic not on Friday, Hindus will avoid beef in particular, and Buddhists should not eat meat at all. Talouselämä 2008.

⁴⁸¹ Cotterrell 2006, 164.

European and Chinese laws have been amended to comply with WTO requirements and, as regards food, the Codex standards⁴⁸². *The EC and China are recipients of international food standards*. The GATT Agreement of the WTO is complemented by the TBT agreement and the SPS Agreement. The latter two agreements have similar requirements: non-discrimination (most-favoured nation treatment and national treatment), avoiding unnecessary obstacles to trade, adopting international standards as far as possible, and the transparency of these measures.

Both the EC and China are selective recipients of international standards. For example with Codex, standards are taken into account by European legislators and courts⁴⁸³ in so far as they are compatible with EC food safety objectives⁴⁸⁴. Similarly, China will not adopt all Codex standards, for example, if differing standards are required to protect the health of Chinese citizens, or if there are specific issues related to Chinese food industry or supervision⁴⁸⁵. This means that where Chinese food producers are capable of producing very safe food, or where China is a net import market, the government is inclined to set standards even higher than those of Codex. In areas where China is a net exporting state, China will, to support its exporters, set lower standards.⁴⁸⁶ Exporters must naturally take into account the standards of the recipient country, which might be either loose or strict.

The WTO has many critics. Some observers claim the WTO agreements are too invasive and deny Members sovereignty; others want the agreements to press further. Some trust national governments on issues related to public health and welfare, whereas others view domestic regulation merely as protectionism.⁴⁸⁷ The two factions claim to have a common goal, which is human well-being. They differ, though, on how best to achieve this goal, either through flexibility, or consensus. As Rawls states, an ideal market process and an ideal legislative process are different entities. Markets are designed for efficacy, and law, if possible, for justice.⁴⁸⁸ Wilkinson sees civil society and development as two areas of the important challenges facing the WTO. NGO's critique the WTO for promoting competition between companies and nations leading to suffering of employees and the environment⁴⁸⁹. Simultaneously, developing countries resist putting environmental and employee rights on the WTO agendas. This opposition stems from the fear that legislation will be used as veiled protectionism, undermining the competitiveness of the South⁴⁹⁰. The WTO needs to be able to satisfy all its Members in order to develop so that it benefits all its Members. Trust is crucial in this vicious circle.

⁴⁸² Kan - Zhang 2002.

⁴⁸³ Codex standards have been referred to by the European Court of Justice. Poli 2004, 616.

⁴⁸⁴ Poli 2004, 616.

⁴⁸⁵ Kan -Zhang 2002.

⁴⁸⁶ Bian 2004.

⁴⁸⁷ Harvard University web page 2004.

⁴⁸⁸ Rawls 1971, 207.

⁴⁸⁹ Wilkinson 2000, 140.

⁴⁹⁰ Wilkinson 2000, 143.

2.4.2 Central vs. Local Laws

When discussing the actors of food and medicine law, the first question to be addressed relates to the roles of international actors such as the WTO vs. central governments vs. local governments.

Globally, the aim of the World Trade Organization is to facilitate trade. Barriers to trade are considered a hindrance to global economic growth, and therefore agreements such as the GATT agreement, the TBT agreement and the SPS agreement aim to remove these barriers. These global agreements have significant impacts on companies and consumers, as they affect whether or not a product can access a certain market. Although free trade has its opponents, lawyers are not openly critical as they⁴⁹¹ are more interested in defining the conditions for *exceptions* to free trade.

In what situations should the EU be able to block Chinese functional foods from entering the EU market? And vice versa? When are they unsafe and/or ineffective? As members of the WTO, EU and China would have to show that based on scientific risk assessment, the products in question are dangerous to human health. Disagreement on the scientific issue would have to be settled by the WTO dispute resolution body. This sets great demands on WTO dispute resolution: it needs to be impartial and transparent, and it needs to be considered *just* to uphold its legitimacy.

According to the law-and-community perspective, international regulation has emerged to express social relations. The desire for a coherent legal order has risen out of collective experience of international communities.⁴⁹² For example, a significant part of environmental advocacy has been directed at multinational economic institutions rather than through state structures. Thus, the environmental movement has contributed to change within the processes of global governance.⁴⁹³ However, as transnational legal authority depends on power politics, structures in international legal orders are fragile.⁴⁹⁴ This is the case with the WTO rules: their content depends on the negotiation powers of the WTO members. National rules are purportedly more stable as they are based on structures of democracy, and - at least to some extent - shared values.

In Europe, the legislative competences of the EU and its Member States are stipulated by the Treaty establishing the European Community. The principles of proportionality and subsidiarity are particularly discussed and weighed in explanatory memorandums of newer laws. The result is today often the same: European legislation is considered necessary. The simple rationale is that free trade would otherwise suffer. European legislation is also considered to better safeguard public health and consumer rights. In the fields of food and medicine law, EU legislation covers progressively more space, and space for Member State law is thus decreasing. Europe-wide industry's self-regulation makes the question of Community competence vs. Member State sovereignty irrelevant. Schepel sees standards as "bottom-up-integration".⁴⁹⁵ It is important to observe that this kind of integration might have happened even without government interference. The EU has certainly accelerated integration, though.

⁴⁹¹ For example Joutsamo et al. 2000, Mäkinen et al. 2006, and Raitio 2006 simply state free trade as a goal.

⁴⁹² Cotterrell 2006, 167.

⁴⁹³ O'Brien et al. 2000, 158.

⁴⁹⁴ Cotterrell 2006, 167.

⁴⁹⁵ Schepel 2005, 73.

Pasa and Benacchio see European consumer law quite positively: “the interventionist policy ... in the area of consumer protection has assumed an important autonomous role, as a social goal of the European Union, and is no longer seen as merely instrumental in the protection of competition”⁴⁹⁶. Critics argue that EU harmonisation is sometimes used unnecessarily and that Member States could better protect the rights of their citizens. Instead of the subsidiarity principle, the most serious hindrance to the transfer of tasks to the European level might be fear that the EU loses societal legitimacy if it initiates cooperation in areas that the majority of Europeans find are illegitimate⁴⁹⁷.

According to the Chinese constitution, local government has the right to formulate local standards if they do not conflict with national standards, or when there are no national standards. Local standards have created problems and barriers to trade. The legal development is also towards national harmonisation in China. Central-local tensions have complicated implementation of laws in China. Local officials are promoted based on their ability to ensure economic growth and social stability, regardless of whether national laws are violated⁴⁹⁸. This means incentives for local officials should be reshaped if enforcing national laws is seen as a priority.

When discussing harmonisation, it is important to notice the difference between minimum and maximum harmonisation. Minimum harmonisation means that local legislators can impose stricter laws if considered necessary to protect their citizens. Maximum harmonisation means full harmonisation in a sense that local legislators cannot deviate from central law in any direction. Maximum harmonisation is often used because it lowers transaction costs for traders. There are obvious problems with maximum harmonisation: it does not serve local variations in society and culture.

In creating internal markets, an alternative to harmonisation is mutual recognition. In the EU, this means that Member States are allowed to have their own standards, but if a product is authorised in one country, it cannot be blocked in another. The resulting overall standard might be lower or higher than with harmonisation. Often, *harmonisation is considered necessary as regards essential features* such as product safety. With regards to other features, harmonisation is not necessary for the creation of an internal market, because mutual recognition applies⁴⁹⁹.

2.4.3 Science vs. Politics

The science vs. politics issue relates to the central vs. local issue discussed above. Local actors will not assign competence to global powers unless they trust them. Global actors need to be impartial concerning local needs. This introduces politics: politics can be seen as promoting the aims of a certain demographic. Global actors need to make decisions based on common good. They have to avoid favouring the most powerful, the most visible, or the most difficult members. With regard to functional foods, this means that law must be based on scientific risk assessment. The science vs. politics issue also relates to the hard law vs. soft law issue discussed above. Legislators will not leave competence in private hands unless they trust them to be impartial, and ‘science’ is seen as objective. In reality, science is always intertwined with politics.

⁴⁹⁶ Pasa – Benacchio 2005, 8.

⁴⁹⁷ Nedergaard 2007, 184.

⁴⁹⁸ Peerenboom 2008 a, 6.

⁴⁹⁹ Joutsamo et al. 2000, 446.

The WTO presumes there is some kind of international objective assessment of the scientific evidence to be found. Schepel claims that the SPS Agreement of the WTO “transparently and pathetically” elevates Codex standards to the status of scientific truth⁵⁰⁰. In this regard the WTO does not have to make ‘political’ decisions, which would spark the legitimacy debate. Based on ‘scientific truth’, the WTO resolves the issue of whether a certain precaution is necessary or not.

The tasks and goals of European and Chinese food and medicine agencies have been discussed above. In the EU, the science vs. politics issue is recognised as common good/public health competing against the interests of national lobby groups. In China, it has been questioned whether legislative efforts are driven by safety concerns (health) or by trade interests (money). Additionally the role of the SFDA has been scrutinised because of the corruption charges against its officials⁵⁰¹.

When discussing the basic tasks of food and medicine law, the following key questions have emerged, both in drafting the law and interpreting it:

- the role of the precautionary principle;
- the role of other legitimate factors besides science.

Firstly, science does not have a solution to everything. It is easy to declare that laws and agency decisions must make consumer health their primary objective. However, it is not always clear whether a certain chemical is dangerous to a person’s health, or whether an herbal substance is effective in preventing a disease. Here we must deal with uncertainty and probabilities. Opinions on necessary precaution vary among scientists and among nations, and need to be continuously discussed.

Secondly, food and medicine law cannot even in theory and particularly not in practice be based merely on science⁵⁰². Other factors such as small business promotion, promotion of local production, employment, human rights and other ethical reasons, etc. might be equally or more relevant. Food and medicine law considers more than just health and consumer protection. However, further discussion is needed on which are acceptable and which are unacceptable “other legitimate factors” besides science. It is accepted that, for example, farmers, businesses, consumers, employees, workers, conservatives, liberals, etc. do not always take the same view. ‘Politics’ is not necessarily a source of all evil: instead it means that in democratic societies, people and organisations are permitted to have different opinions. These opinions, however, need to be weighed in a manner that legitimate rights of some groups are not suppressed. Once agreed upon, regulations need to be applied in an unbiased manner, both nationally and globally. Clearly, corruption cannot be tolerated.

According to Bian, it might be typical in developing countries that trade interests are the governments’ foremost concern. As China produces more agricultural products than it needs, its support of exports is very important.⁵⁰³ In the future, the Chinese focus might shift onto

⁵⁰⁰ Schepel 2005, 222.

⁵⁰¹ Tsoi 2007.

⁵⁰² In the new European Nutrition and Health Claim Regulation 1924/2004/EC, it is stated (preamble 30), that “In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. Other legitimate factors relevant to the matter under consideration should therefore be taken into account.”

⁵⁰³ Bian 2004.

creating more effective national markets. The EU has also been criticised for attaching too much importance to trade. Facilitating exports and imports is important to Europeans, but not as important as guaranteeing the function of the European internal market. After all, the European internal market consists of 27 countries of interest as market areas.

Schepel views modern governance as linking the political, the scientific, and the economic spheres of life. Standards bodies are an example of such a link: they connect the global marketplace to national politics, scientific knowledge to industrial practice, and social custom to law.⁵⁰⁴ Emotional aspects are part of social customs. Regulations intended to protect human health are often contentious, as people's fears and scientific evidence do not always correlate. Here, emotions are seen as obscuring objective science.⁵⁰⁵ Emotions such as fear, love, hate, or guilt will perpetually encircle science and law.

2.4.4 Hard law vs. Soft law

Both in the EU and in China, and both in regulation of foodstuffs and medicines, *the role of regulatory agencies is very important*. In Europe, this refers to the EFSA and the EMEA, along with all the Member State agencies. The agencies are involved both in drafting the laws and implementing the laws. In China, administrative organs, such as the ministries and the SFDA, provide regulations that are called *guizhang*. Some of the most important hard laws, for example the General Food Regulation in the EU and the Food Safety Law in China, are quite basic and general, lacking detail. The details are given by administrative instruments, which can be called *soft law*. This means that a large part of foodstuff and medicine regulation is given by the administrators, not the legislators and that this is also the part that is particularly relevant from the entrepreneur's perspective.

The binding nature of 'guidelines', 'notifications', 'procedures', etc. varies. In China, many actors typically have competence over the same issues, but still do not have to take regulations of other actors into account. This leaves regulation targets in an unclear situation regarding which regulations to follow. In Europe, soft law guidelines are typically attached with statements of the type "this is not binding; only the laws are binding". This also leaves entrepreneurs legally insecure: the agencies presume that soft law guidelines are followed, but guidelines can suddenly be abolished or changed, or not be adhered to in individual cases.

In China, with both foodstuffs and medicines, one basic law given by the Congress is supplemented by several pieces of legislation given by the Ministry of Health, other ministries, or by the SFDA. Soft law includes all the scientific, technical and procedural details. This division of work between the Congress and the various other authorities has meant that a new law is not included in the basic law or any other piece of regulation. Instead, a separate piece of regulation is given on each issue. In the future, soft law on both foodstuffs and medicines might be codified or collated together in China. In Europe, the EMEA has collated the regulatory materials on medicines into volumes combining hard law and soft law materials. This enables entrepreneurs to fully understand the regulations affecting their business. Similar collections could be published by the EU on food law.

⁵⁰⁴ Schepel 2005, 35.

⁵⁰⁵ Harvard University web page 2004.

Standards have been discussed above as being something in between the public and the private. Standards are seen as facilitating growth and trade, and also as the answer to calls for better regulation. The European Commission sees standards as a new approach to legislation. As standards gain importance, effective participation in standard-making of all interested parties needs to be guaranteed⁵⁰⁶. International standards were recently discussed at a WTO Technical Barrier to Trade workshop. It was stressed that during economic crisis, standards should not be used for protectionist purposes, and also that developing countries need to be involved in setting up international standards.⁵⁰⁷

According to Koulu, the area of soft law will likely broaden in the future. Soft law is favoured by actors who produce it because it is fast and inexpensive as there is no need to find a political compromise. The experts can merely draft soft law and publish it. Koulu points out that scientific expertise of law-makers will not automatically lead to high quality laws. Calls for *better soft regulation* have not emerged, although better regulation as regards hard law has received much attention. Soft law is beyond quality control, as the producer of soft law can revert to the fact that soft law is non-binding. Problems of legislative competence, legal coherence, legal interpretation, or legal protections for regulation targets can similarly be avoided.⁵⁰⁸ Simultaneously, normative terms are used perhaps to make regulation targets overlook the non-binding nature of soft law⁵⁰⁹.

Food and medicine law are typical areas where the above-mentioned reasons for soft law and its related problems apply. Detailed food and medicine law is typically given by experts, not legislators. Soft law is followed in practice, however, there is still not enough scientific discussion on competence or soft law quality. Critical evaluation of soft law and its makers is necessary in the field of foodstuffs and medicines. Soft law cannot be ignored merely because it is by definition classified as non-binding. Discourse theories define the frameworks for making decisions, for example on law⁵¹⁰. In democratic discourse theories, laws are seen as collective decisions for common good, as battle results, or as something in between⁵¹¹. Tuori sees discourse in the civil society necessary both when laws are made and when they are implemented⁵¹². Concerning food and medicine law, the civil society consists of companies, consumers, healthcare organisations, etc., whose involvement in law-making is necessary to uphold legitimacy.

Sideri sees the current development of law as a move away from “government” to “governance”, from the formal legal order to informal ones. There is a shift of attention from representative democratic structures to engagement of citizens in new governance structures, from command and control rules to procedural rules communicating local knowledge, from the sovereign state to the responsible citizen, and from hierarchies to networks.⁵¹³ Sideri sees “compromise” as a cognitive lens, through which law is to be examined. Laws reflect

⁵⁰⁶ The Commission lists NGOs, environment, consumers, SMEs, authorities, and business representatives. Commission Communication on Standards 2004, 9.

⁵⁰⁷ WTO news items 16 and 17 March 2009. Available on WTO home page at: http://www.wto.org/english/news_e/news09_e/tbt_16mar09_e.htm.

⁵⁰⁸ Koulu 2009, 119-120.

⁵⁰⁹ Koulu 2009, 121.

⁵¹⁰ See Habermas 1992.

⁵¹¹ Sassi 2000.

⁵¹² Tuori 2000, 300.

⁵¹³ Sideri 2007, 2-3.

temporary balances, bound to change again, especially in decentralised governance structures where interested parties are engaged in the decision-making process.⁵¹⁴ Laws can thus be seen as products of communication between agents and structures⁵¹⁵. In the field of foods and medicines, we could see companies as citizens communicating their interests to authorities and the public, and legislators as governors who provide the necessary structures and facilitate this correspondence.

According to Schepel, law is in crisis. It cannot answer to the needs of modern, international societies. Like Sideri, Schepel discusses the shift from “government” to “governance”. Distinctions between public and private roles and values are becoming fluid, and the locus of regulating is shifting from the state to other, multiple, locations⁵¹⁶. If law and state were one, we could subjugate all private transnational rulemaking under national legal hierarchies stemming from national constitutions. Globalisation and private governance regimes break this mould and we need to redefine law itself. Schepel sees law as a coupling between fragmented social discourses⁵¹⁷. Law as a product of nation-state politics might be in crisis, particularly if we look at international business. However, there is more to law than harmonising products. National legislation still covers many elements of societies and markets where functional foods are used: healthcare, school lunches, taxes on different products, media.

The concept of *legal certainty*⁵¹⁸ might have to be reformulated in the new modes of governance. If law was seen as a temporary compromise between stakeholders, protecting legitimate expectations would mean protecting reliance on the communicative and interest-balancing *process* of law-making *itself*, not so much on predictability of legal rules or their implementation. The imperative for legal policy would be *co-ordinating* public and private rulemaking⁵¹⁹: promoting procedural integrity of the regulators, diversifying their membership, and enhancing their knowledge base⁵²⁰.

2.4.5 Pre-market vs. Post-market Control

As their key task, food and medicine control agencies are responsible for *pre-market control* of foodstuffs and medicines. Pre-market control means deciding, based on scientific criteria, whether the products are safe and effective. Pre-market control has always been the dominant regulatory mechanism for medicines, and today it is also often needed for foods. Besides scientific assessment of safety and efficacy, the agencies also decide on the application and authorisation procedure itself, for example on how to draft the applications. Impartiality and

⁵¹⁴ Sider 2007, 58.

⁵¹⁵ Sideri 2007, 126.

⁵¹⁶ Schepel 2005, 31. Schepel refers to Black, Julia: Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in “Post-Regulatory” World. *Current Legal Problems*. 2001.

⁵¹⁷ Schepel 2005, 34.

⁵¹⁸ Legal certainty forms an important aspect of most legal systems. It operates with sub concepts such as non-retroactivity and legitimate expectations. Protecting legitimate expectations means that good faith is respected: if parties in question firmly believe a particular course of action will be followed and it is reasonable for them to do so, they may rely on that expectation. The government can, however, violate their faith if it is necessary in order to protect the public interest. Jason-Lloyd 1997, 6.

⁵¹⁹ Schepel 2005, 32.

⁵²⁰ Schepel 2005, 413.

equal treatment of applicants is crucial. This notion was demonstrated in China because a key official of the SFDA was executed for taking bribes. In China, the pre-market control procedures have been accused of being too complex and burdensome. Also the protection of intellectual property has been questionable and made some companies reluctant to apply for product registration in China.

Post-market control is also vital. Enhancement of supervision of foodstuffs and medicines is currently foremost on the agenda of the Chinese government. The Chinese aim to enhance product safety, and to promote social harmony and stability. This means, “establishing a coordinated supervision mechanism and upgrading the technical level of inspections and scientific testing”.⁵²¹ Also in Europe, enhancing control has been one area of focus.

It is an important legal starting point that operators themselves carry the primary responsibility for safety control, both pre-market and post-market. As companies have expertise on their own products, they should also carry the risks associated with their marketing. With foodstuffs, in-house control is often the most important - and sometimes the only - type of control. With medicines, the role of administrators is stronger as all medicines are subjected to pre-market registration. However, the ultimate responsibility always lies with the operators themselves.

Penalties are needed for breaking the rules on product safety and marketing. In Europe, penalties have not been used often, and there have been demands that punishments should be harder. The lack of criminal trials is considered a positive phenomenon: the system seems to work if penalties are rarely needed. The authorities have wide powers, but there is still a sense of cooperation in implementing the rules. More than orders, implementation seems to consist of negotiations and persuasion. Sometimes the negotiation approach might in practice be due to the fact that it is *cheaper* than going to courts.

In China, administrative penalties are stipulated rather accurately beforehand in yuan amounts. These administrative penalties are automatic with no room for consideration. Chinese legislators see that this is the best way to guarantee equality. Imposing penalties is thus often administrative work, and the court system is not as relevant as in Europe. This is due to the deep-seated norm against legal proceedings. Litigation in Chinese courts is increasing, but courts are still weak and depend on local governments for financial support and enforcement⁵²². China’s initiatives to enhance judicial independence may change this situation. China is taking steps to facilitate enforcement of judgments so that local protectionism will not be a hindrance⁵²³.

In China, several different government agencies create the laws⁵²⁴. The same authorities are also responsible for the implementation. It is important to notice that in China, legislation has been created very quickly in the past 30 years and implementation lags behind. Laws are typically

⁵²¹ Five-Year Plan for Food and Drug Safety. April 2007.

⁵²² Wikipedia. http://en.wikipedia.org/wiki/Chinese_law.

⁵²³ Peerenboom 2008 b, 3.

⁵²⁴ Food safety for the Chinese domestic market is regulated by several government entities: the Ministry of Agriculture, the Ministry of Health, the Ministry of Commerce, the State Administration of Quality Supervision, Inspection, and Quarantine, and the State Food and Drug Administration. These entities have different and sometimes overlapping responsibilities. The State Administration of Quality Supervision, Inspection, and Quarantine is responsible for imported as well as exported goods. The SFDA oversees all medicines, both Western and traditional Chinese medicines, including their advertising.

stricter than reality. This situation allows the government to flexibly and suddenly tighten control, based on law⁵²⁵. Legislation thus features *goals* or *options* rather than reality.

The Chinese Food Hygiene Law and Chinese administrators have been criticised for focusing too much on punitive measures and too little on preventive measures such as inspection sites or mandatory safety criteria.⁵²⁶ It is easier to impose penalties instead of facing the enormous task of building the regulation of entire product chains on trust and negotiations. Food and medicine control is particularly challenging due to the huge size and diversity of the country.

The Chinese government seems to be dealing with this directly: the administration is restructured and competences are reassigned. This should allow the authorities at least to be aware of their competences and tasks, which is a good foundation. Authorities and their expertise are needed to help regulation targets implement the laws in practice. The new Food Safety Law of 2009 creates a new state-level Food Safety Commission to oversee food safety monitoring. This Commission will consist of members from the Ministry of Health, the Ministry of Agriculture, the General Administration for Quality Supervision and Inspection and Quarantine, State Food and Drug Administration, and the State Administration for Industry and Commerce.

⁵²⁵ Welin – Kaulo 2005.

⁵²⁶ Li 2005, 29.

3 FUNCTIONAL FOODS: FOODSTUFFS OR MEDICINES?

In this chapter, we aim to *define the boundaries of two legal foodstuffs and medicines*. These are the two most important legal concepts for the purposes of this study. This includes reviewing the *legal status of functional foods*.

This chapter forms the background for subsequent chapters, which review the law on safety of foodstuffs and medicines (chapter 4), and the law on marketing of foodstuffs and medicines (chapter 5).

3.1 Legal Concepts and their Functions

According to Tuori, legal concepts are important in systematising surface-level legal material.⁵²⁷ New legislation does not function in isolation but is inserted into the legal order's totality. Location of new legislation in this totality is determined by legal concepts. Through the legal concepts, material legislation finds its place in the legal order.⁵²⁸ Legal concepts of 'food' and 'medicine' have the important task of systematising the legal material that governs functional foods as we have determined them in chapter 1. The two concepts divide products into two categories, for which separate parts of the legal order apply.

Legal concepts are not legal terms. Terms are linguistic phenomena, whereas concepts are semantic phenomena. Concepts are meaning-contents or thought-contents, which can be expressed through one or more terms.⁵²⁹ This means that the terms 'food', 'foodstuff' and 'elintarvike' (the Finnish word for food) all express the same concept, i.e. they are synonyms. 'Medicine' and 'drug' also express the same concept, whereas 'pharmaceutical' sometimes refers to chemical medicines only. Naturally, 'food' and 'medicine' are also, for example, sociological and medical concepts. Each field of science needs to create their own concepts. Legal concepts are formed by lawyers, whereas, for example, medical concepts are formed by doctors.

Lawyers must define legal concepts in order to be able to create and work with legal material. Law-making is not a single process leading to a single legal decision. Instead, law is made in several processes leading to the production of a legal concept.⁵³⁰ The legal concepts

⁵²⁷ Legal concepts are products of the legal culture that lies beneath the surface. Legislation and court cases are the surface. Tuori 2002, 169.

⁵²⁸ Tuori 2000, 192-193.

⁵²⁹ Frändberg 1983, 84.

⁵³⁰ Zamboni 2008, 523.

of ‘food’ and ‘medicine’ have been formed through legislation and court cases, as will be described below. These concepts can also be developed through jurisprudence. Legal concepts are not static: they are continuously clarified, reformulated, and redefined. It is worth noting that *legal concepts might be abolished or replaced by other concepts*.

Rationalism is the ideological base that ties law formation and concept formation together⁵³¹. Legal concepts can be defined as rules aiming to build *rationality of the law*. Rationality is built in an interaction where different concepts are coordinated and combined to build a rational system. Rationality of the law is not an objective question. It depends on the legal system under consideration, and theoretical assumptions of the observer. Rationality can have both formal criteria such as consistency and coherence, and substantial criteria such as justice or economic efficiency.⁵³² These criteria of rationality can be applied also to the legal concepts of ‘food’ and ‘medicine’.

Legal concepts are lenses through which *lawyers* see the world⁵³³. However, when defining legal concepts such as ‘food’ and ‘medicine,’ legislators and courts need help from scientists of other fields. The separation between foodstuffs and medicines is a question of nutrition, health policy, business opportunities, and consumer behaviour. Besides lawyers themselves, experts of all these other fields must acknowledge the legal concepts. Legal concepts affect consumer choice and thus presumably public health. Because of the wide-reaching implications, legal concept formulation deserves consideration, and re-consideration when necessary. Business law is an interaction where legislators and courts respond to the market situation, and markets in turn respond to law. This is also the case in regulating functional foods. By calling business law interaction, we do not see law as merely about removing social friction⁵³⁴. Law is also a question of values: law should guide ethical behaviour.

3.2 Europe: Foodstuffs vs. Medicines?

In Europe, the national authorities determine whether a product is a medicine or a food. This categorisation decision is based on European definitions of foodstuffs and medicines. However, these definitions leave room for interpretation. The European Court of Justice will ultimately decide how the EU definitions are to be interpreted. The national authorities will have to follow the ECJ practice.

3.2.1 Definitions in Legislation

Codex Alimentarius⁵³⁵ defines food as:

“Any substance, whether processed, semi-processed or raw, which is intended for human consumption, including drink, chewing gum and any substance which has been used in the

⁵³¹ Frändberg 1983, 115. Rationalists believe that rational structures can be created by rational thinking.

⁵³² Zamboni 2008, 523.

⁵³³ Tuori 2002, 51.

⁵³⁴ See Pöyhönen 1997, 248.

⁵³⁵ The UN ‘food code’, jointly made by FAO and WHO. Codex was discussed above in chapter 2.

manufacture, preparation or treatment of ‘food’”. *Food does not include* cosmetics or tobacco or *substances used only as drugs*.⁵³⁶

In the EU, a product can be regarded as a medicinal product either by its marketing claims or by its functions. The definition of ‘medicinal product’ in the EU medicinal products directive⁵³⁷ is the following:

“Medicinal product:

- (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or in making a medical diagnosis.”

Of the different functions that medicinal products have, restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action have implications for functional foods. Making a medical diagnosis is something a functional food would not do.

The definition in the Medicinal Products Directive was made to encompass all products designed or claiming to deliver a preventive, therapeutic or curative effect, including not only products having a genuine effect but also those which are not sufficiently effective or do not have the effect which consumers might expect from their presentation. By submitting all products with medicinal functions and claims to a common licensing procedure, it was considered that effective and consistent consumer protection could be ensured, not only from harmful toxic products as such, but also from a variety of products being used instead of proper, effective remedies.⁵³⁸

*The definition was changed by the Directive 2004/27/EC*⁵³⁹. It was then added that there had to be a *pharmacological, immunological or metabolic action*, if the product is to be regarded as a medicinal product by function. The new definition thus specifies the type of action that the medicinal product may exert on physiological functions⁵⁴⁰. The previous definition only stated, “modifying physiological functions” without specifying different types of ‘actions’ through which these ‘functions’ are modified. ‘Physiological functions’ clearly mean the functions of the living organism, the physical body. The terms ‘pharmacological’, ‘immunological’ and ‘metabolic’ are more difficult to understand and although they are decisive here, they are not defined in the directive. The terms still leave room for interpretation on what is considered a medicinal function.

⁵³⁶ Codex General Standard for the Labelling of Pre-packaged Foods (1985), 8.

⁵³⁷ Article 1(2).

⁵³⁸ Coppens et al. 2001, 141.

⁵³⁹ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. The former definition was the following: “Medicinal product: Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product”.

⁵⁴⁰ Preamble 7, directive 2004/27/EC.

According to the Cambridge Advanced Learner's Dictionary, 'pharmacology' means the study of medicines and drugs, including their action, their use and their effects on the body.⁵⁴¹ According to Elhurst University⁵⁴², medicines can be divided into main groups according to the following different types of *pharmacological actions*:

- a) Chemotherapeutic agents used to cure infectious diseases and cancer⁵⁴³,
- b) Pharmacodynamic agents used in non-infectious diseases⁵⁴⁴, and
- c) Miscellaneous agents such as narcotic analgesics and local anaesthetics.

Immunity means the ability of the body to resist pathogens⁵⁴⁵, i.e. agents that cause diseases. 'Immunology' means the study of immunity and its causes and effects.⁵⁴⁶ Immunological disorders are conditions where the immune system fails to function properly, such as AIDS. '*Immunological action*' in the definition of medicinal product thus means something that modifies, corrects or restores physiological functions by affecting the immune system.

According to the Cambridge Advanced Learner's Dictionary, metabolism means "all the chemical processes in your body, especially those that cause food to be used for energy and growth".⁵⁴⁷ Metabolic processes are organic processes that are necessary for life. '*Metabolic action*' in the definition of medicinal thus means something that modifies, corrects or restores physiological functions by affecting the metabolic system. This could be interpreted to mean almost anything that happens in the body to keep the body alive.

It seems that foods could have 'pharmacological', 'immunological' or at least 'metabolic' actions. It seems complicated to define medicines in a manner that would clearly exclude foods. A category of "borderline" products has emerged. The European Commission tried to resolve the issue of these borderline products by Directive 2004/27/EC. According to preamble 7 of the Directive, the definition of medicinal products and simultaneously the scope of the Medicinal Products Directive needed clarification particularly as a result of scientific and technical progress. It was stated that there is a growing number of "borderline" products between the medicinal product sector and other sectors. The aim was to modify the definition of medicinal product so as "to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products".⁵⁴⁸

Preamble 7 continues: "it is necessary, in case of doubt and in order to ensure legal certainty, to state explicitly which of the two colliding provisions have to be complied with". Where a product comes clearly under the definition of other product categories, for example food and food supplements, the medicinal product directive does not apply.⁵⁴⁹ New Article 2(2) gives the answer in situations where the case is not clear: "*In cases of doubt*, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and

⁵⁴¹ Cambridge Advanced Learner's Dictionary.

⁵⁴² Elmhurst University web page: Virtual Chemistry book.

⁵⁴³ Sulfa drugs, antibiotics.

⁵⁴⁴ Cholinergic, Adrenergic, Hallucinogenic, Sedatives.

⁵⁴⁵ The Free Dictionary. <http://www.thefreedictionary.com/immunity>.

⁵⁴⁶ Cambridge Advanced Learner's Dictionary.

⁵⁴⁷ Cambridge Advanced Learner's Dictionary.

⁵⁴⁸ Preamble 7, directive 2004/27/EC.

⁵⁴⁹ Preamble 7, directive 2004/27/EC.

within the definition of a product covered by other Community legislation *the provisions of this Directive shall apply*". This means *a product is in unclear cases classified as a medicine*.

The definition of food in the EU General Food Regulation does not offer any guidance on the categorisation issue:

"For the purposes of this Regulation, "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC⁵⁵⁰ and without prejudice to the requirements of Directives 80/778/EEC⁵⁵¹ and 98/83/EC.

"Food" shall not include:

- a) feed;
- b) live animals unless they are prepared for placing on the market for human consumption;
- c) plants prior to harvesting;
- d) *medicinal products* within the meaning of Council Directives 65/65/EEC(21) and 92/73/EEC(22)⁵⁵²;
- e) cosmetics within the meaning of Council Directive 76/768/EEC(23)⁵⁵³;
- f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC(24)⁵⁵⁴;
- g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- h) residues and contaminants."⁵⁵⁵

This means that when it comes to products ingested for health reasons, such as functional foods, the definition of 'food' covers everything that is left outside the definition of 'medicinal product'. A product always has to be either a food or a medicine, not both. The Medicinal Products Directive refers to medicinal products as "...substances or combination of substances...". Substance is defined as "any matter irrespective of origin which may be human, animal, vegetable or chemical. Foods are substances or combinations of substances within this broad definition. Therefore, the *raw materials* themselves do not determine the classification of a product as food or medicine."⁵⁵⁶

⁵⁵⁰ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

⁵⁵¹ Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters.

⁵⁵² These Directives were codified and replaced by the Directive on the Community Code Relating to Medicinal Products for Human Use 2001/83.

⁵⁵³ Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

⁵⁵⁴ Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products.

⁵⁵⁵ Article 2.

⁵⁵⁶ Coppens et al. 2001, 142.

3.2.2 European Court of Justice: Case Law

As stated above, Article 1 of Directive 2001/83/EEC defines a “*medicinal product*” as:

- (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.”

Medicinal products may well fall under both limbs of the definition but the European

Court of Justice (ECJ) has confirmed that falling under either limb is sufficient to classify it as a medicinal product. [*Upjohn 1989*]: “*Directive 65/65 provides two definitions of the term “medicinal product”: one relating to presentation, the other to function. A product is medicinal if it falls within either of those definitions.*”

If we look at the ‘claim’ part of the definition, the ECJ has placed considerable emphasis on the impression that consumers are likely to form as a result of the product’s presentation. [*Van Bennekom 1982*]: “It is necessary to take the view that a product is presented for treating or preventing disease... whenever any averagely well-informed consumer gains the impression, which provided it is definite, may even result from implications, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the EC definition.”

The ECJ attaches importance to protecting vulnerable consumers from products that could not deliver the claimed medicinal results. [*ibid*]: “The Directive thereby seeks to protect consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies.”

The ECJ has ruled⁵⁵⁷ that a product does not necessarily need to be presented explicitly for the prevention or treatment of human diseases to trigger medicinal status. A medicinal status may arise from the impression that an average, well-informed consumer would be likely to gain. This may derive from aspects such as the product’s composition, pharmacological properties, claims and associated commercial and non-commercial communication, its presentation (including any similarity to medicinal products) and point of sale, any risk arising from prolonged consumption, the way it is used, and its familiarity to the consumer.

The question whether or not a product is perceived as “medicinal” will be resolved, primarily, by reference to the balance of medical and non-medical uses *on the label or advertising* and not to the likelihood of sales for one use rather than another. The nature of the product’s constituents is not usually the decisive factor, although if a product contains therapeutic levels of pharmacologically active substances, this could well result in it being considered a medicine, even if the base-line product is clearly a food. In reality it is likely that well established food products would be considered as foods and well-established medicines as medicines.⁵⁵⁸

⁵⁵⁷ Case C227-82.

⁵⁵⁸ Coppens et al. 2001, 143.

On a literal interpretation of the existing legal texts, any food carrying a medicinal claim would become subject to medicinal legal procedures and would require a Product Licence. No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State⁵⁵⁹ according to the Directive 83/2001/EC.⁵⁶⁰

In *Ter Voort* case⁵⁶¹, the European Court of Justice ruled that a product that is recommended or described as having preventative or curative properties is a medicinal product even if it is generally considered as a foodstuff and even if it has no known therapeutic effects in the present state of scientific knowledge. Conversely, the advertising of a medicinal product to the general public shall not contain any material, which suggests that the medicinal product is a foodstuff⁵⁶². This means that if a food-based product makes a medicinal claim, it is a medicinal product, probably an illegal one.

As previously stated, a product can be considered as a medicinal product based on its functions as well as its claims. It has long been recognised that certain foods are able to restore and correct disturbed physiological functions caused by nutrient deficiencies, e.g. vitamin C rich foods will cure scurvy, iodized salt will restore thyroid function, and vitamin A rich food will restore night vision. Recent scientific literature amply and increasingly indicates that many other foods are able to restore, correct or modify physiological functions by virtue of the non-nutrient substances they contain.⁵⁶³ This means we could classify almost all foods as medicines.

In law, all foods can be considered medicinal products if ingested with the view to restoring, correcting or modifying physiological function. The Advocate General's Opinion in the *Delattre* case⁵⁶⁴ states that the function-based definition of medicinal products is formulated in such broad terms that, if read literally, it can apply both to medicinal products and foods.

It is important to note that the *Delattre* case occurred in the period before the new definition where medicinal action is specified as "modifying physiological functions by exerting pharmacological, immunological, or metabolic action". As discussed above, the terms 'pharmacological', 'immunological', and 'metabolic', still do not exclude foods. Our science-based understanding on the relationship between diet and health seems to make it impossible to define medicines in a manner that would clearly exclude foods. That is why the legislators decided to establish the unofficial borderline category of "unclear cases", at the same time directing these products under medicine law.

The European Court of Justice (ECJ) has ruled that it is the competence of Member States' National Authorities to judge whether a product is a food or a medicinal product. The consequence of this is that there cannot be legal certainty at a European level. National

⁵⁵⁹ A marketing authorisation for a medicinal product granted by a competent authority in one Member State ought to be recognized by the competent authorities of the other Member States unless there are serious grounds for supposing that the authorisation of the medicinal product concerned may present a risk to public health (Recital 12.)

⁵⁶⁰ Some products are subjected to a centralised authorisation procedure according to Council Regulation No 2309/93 of 22 July.

⁵⁶¹ Case C219-91.

⁵⁶² Medicinal Products Directive, Article 90(g).

⁵⁶³ Coppens et al. 2001, 142.

⁵⁶⁴ Case C369-88.

definitions might be broader than the European definitions.⁵⁶⁵ According to the European Food Lawyers Association, the borderline between foodstuffs and medicinal products is one of the remaining food law problems to be resolved. They see the situation where the categorisation decision lies with Member States as a severe obstacle to the achievement of the Single Market. The regulations on food supplements, fortified products and nutrition and health claims have greatly harmonised the area of health-promoting foods.⁵⁶⁶ The proposed labelling regulation will continue this development, leaving only the issue of food vs. medicine unharmonised.

As the foodstuff vs. medicine issue is still under the competence of EU Member States, we will examine the Finnish and UK strategies to cope with the categorisation task. The British system is fairly developed and might serve as a model for future EU system performed by the EFSA or the EMEA.

3.2.3 Finnish Practice

According to section 6 of the Finnish Medicinal Products Act, when necessary, the National Agency of Medicines (Lääkelaitos) determines whether or not a product is a medicine. When making the decision of categorisation, both the composition and the purpose of use are taken into account. The Food Act or other food legislation does not affect the decision. For medicinal products, the national authorities also resolve the retail channel of a medicinal product (pharmacy only or other stores as well), and whether a medicine requires a prescription or not.

The National Agency of Medicines has published a Pharmacopoeia (1179/2006), where all the ordinary medicines and herbal medicinal products are listed. According to section 1 of the Pharmacopoeia, other substances and herbs that are medically equivalent to those listed and used in a medicinal way can be held as medicines. Also vitamin or mineral preparations, where the daily dose exceeds the limits in the pharmacopoeia can be held as medicines, as well as vitamin or mineral preparations for children.

If it is unclear whether the product to be placed on the market is a medicine or not, the National Agency for Medicines will, on request, classify the product. It will normally do this only on request and requires a fee⁵⁶⁷. Information on the product should be submitted to the Pharmacovigilance Activities unit of the National Agency for Medicines for the decision on classification.⁵⁶⁸ The National Agency for Medicines can also without request classify a product as a medicine, if it complies with the definition of medicines.

The Food Safety Agency is also involved in classification. It “recommends” a marketer to apply for a classification decision if a food contains substances or herbs listed in the pharmacopoeia, or if the amount of vitamins or minerals exceeds the set limits. If the Food Safety Agency itself notices that a food supplement contains medicinal materials, it will specifically recommend the marketer to apply for a classification decision. The Food Safety

⁵⁶⁵ Coppens et al. 2001, 142.

⁵⁶⁶ European Food Law Association. Letter to the Commission. January 2007.

⁵⁶⁷ The fee was 85 euros in 2006.

⁵⁶⁸ National Agency for Medicines web page. http://www.nam.fi/english/pharma_industry/herbal_remedy/herbal_medicinal_product/index.html.

Agency also notifies the National Agency for Medicines of its recommendation.⁵⁶⁹ Because of the pre-market notification procedure for food supplements, it is easy for the Food Safety Agency to follow what is put into food supplements. This is not the case for functional foods, for which there is not necessarily any pre-market clearance.

Dosage is the key word in determining whether a product containing medicinal herbs, vitamins, or minerals is regarded a medicine. This means *the distinction between medicines and foodstuffs is often (merely) gradual*. With vitamins and minerals, the medicinal doses are set beforehand. With herbs, there is more room for discretion. We will look into Finnish examples of medicines and non-medicines in chapter 6 when trying to predict how our fictional products will be classified.

The system of voluntary clearance will lead to some products with medicinal effects being sold as foods. It is not mandatory to get a product classified even if it contains medicinal herbs. One can just sell the product as a food and wait to see if the Food Agency and the Medicine Agency react. After products are classified as medicines, the marketer must withdraw products from food stores.

3.2.4 UK Practice

In the UK, ‘borderline product’ is a term for products that are not easy to distinguish from a medicine, for example, cosmetics or food supplements⁵⁷⁰. The decision of whether a product is a medicine is based on its functions and its marketing, as stipulated in the medicinal products directive. Normally, a product which is for use only as a toilet preparation, disinfectant, food or beverage is not regarded as a medicinal product, and, therefore, does not require a marketing authorisation. Similarly, dietary supplements, containing such familiar substances as vitamins, amino acids or minerals, are generally subject to food safety and marketing rules rather than medicines control.⁵⁷¹

However, should any of the above contain *a pharmacologically active substance* or *make medicinal claims*, it would be regarded as a medicine. Medicinal claims are, according to MHRA, claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body⁵⁷². The definition of a medicinal claim is of course based on the longer definition in the directive, but the UK definition is worth mentioning, as every EU member state will see the concept of ‘medicine’ a bit differently, which will influence the division of foods and medicines. Presenting medicinal claims in labelling and advertising will make any cosmetic or food a medicinal product.

The MHRA’s Borderline Section, similarly to the Finnish NAM, offers advice on the status of a product in cases of doubt. The MHRA’s Borderline Section has an online “Borderline Medicine Advice Form” for this purpose. A full reply is promised “in due course”. In making a decision, the MHRA considers “each individual product on its merits and any information which

⁵⁶⁹ The Food Safety Agency Guideline on Food Supplements. Updated December 2006.

⁵⁷⁰ MHRA web page. http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009271&ssTargetNodeId=91.

⁵⁷¹ MHRA web page. http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009271&ssTargetNodeId=91.

⁵⁷² MHRA web page. http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009271&ssTargetNodeId=91.

may have a bearing on the product's status, for example, the claims made for the product, the pharmacological properties of the ingredients, whether there are any similar licensed products on the market, and how it is presented to the public through labelling, packaging, promotional literature and advertisements".⁵⁷³

The MHRA has also issued a guidance note related to borderline products. Guidance Note 8, '*A guide to what is a medicinal product*' provides detailed information and is intended for the guidance of companies who need to consider whether products they propose to place on the market are medicinal or not⁵⁷⁴. The food vs. medicine -issue is discussed in sections 7 and 8 of the guidance note. "Food" is defined as any food, drink or food supplement that is part of the diet. Every ingested product is either a food or a medicine. Also articles and substances of no nutritional value are foods. A product, which the average consumer would regard as something to be eaten, drunk or chewed as part of his/her diet, for example, because of its taste, flavour, or nutritional value, is unlikely to be classified as a medicinal product. However, if the product contains *one or more ingredients generally regarded as medicinal and indicative of a medicinal purpose*, it will likely be classified as a medicine.⁵⁷⁵

In the guidance note, relevant guidance issued by the Local Authority Coordinating Body on Trading Standards (LACOTS) and the Joint Health Claims Initiative's published Code of Practice are also referred to. It is also emphasised, that foods for particular nutritional purposes (dietary foods), including dietary foods for special medical purposes, are under separate EC and UK legislation.⁵⁷⁶

The MHRA reaches a determination as to whether a product is a medicinal product on a case-by-case basis, and in the light of:

- the definitions of medicine and food;
- relevant ECJ and UK precedents; and
- an assessment of all the available evidence.⁵⁷⁷

Nothing definitive can be said about the weight of different pieces of evidence. It is stated that no single factor or combination of factors will necessarily be conclusive, or more or less important than others. On the contrary, a single factor or combination of factors may be more important than others, and may even be conclusive.⁵⁷⁸

Medicine based on claims

In assessing whether a product is "*presented for treating or preventing disease*", the MHRA considers, explicit and implicit claims which are made for it, and with reference to its *presentation as a whole*. Claims of relief from symptoms, or to cure, remedy or heal a specific disease or adverse condition of body or mind will also be regarded as medicinal claims. If

⁵⁷³ MHRA web page. http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009271&ssTargetNodeId=91.

⁵⁷⁴ MHRA web page. http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009271&ssTargetNodeId=91.

⁵⁷⁵ Guidance note, paragraph 7.

⁵⁷⁶ Guidance note, paragraph 8.

⁵⁷⁷ Guidance note, paragraph 14.

⁵⁷⁸ Guidance note, paragraph 14.

the product, for example, claims to help cope with stress, anxiety and nervous tension, these are considered claims to treat or prevent disease. Claims to “protect” or “avoid” may be perceived by consumers as having much the same meaning as “prevent”, and would thus also be considered medicinal claims.⁵⁷⁹

The MHRA does not consider claims to “maintain” or “help to maintain” or “support” health or a healthy lifestyle, as medicinal in themselves. The key is whether the product is a) said to maintain health or b) to restore some function or organ to a normal state. The latter claim would in the UK be considered medicinal.⁵⁸⁰

To further help the applicants, the MHRA has listed factors particularly relevant to deciding whether a product is a medicine under the first part of the definition (medicine based on presentation). These are:

- all claims made for the product, both explicit and implicit, including any made on linked “helplines” or in linked publications. “Implicit” claims may include product names.
- the context in which the claims are made, and the overall presentation;
- how a product appears to the public, or to those to whom it is promoted;
- the labelling, and packaging/package inserts including any graphics;
- the promotional literature, including testimonials and any literature issued by a third party on behalf of the supplier;
- advertisements, including those appearing in “advertorials”, on television, other media and the Internet;
- the product form, (capsule, tablet, etc.) and the way it is to be used;
- any particular target of the marketing information/advertising material, for example, population groups with, or particularly vulnerable to, specific diseases or adverse conditions.⁵⁸¹

In addition to general criteria for evaluating marketing, The MHRA has also produced an indicative list of the kind of claims that the MHRA may decide are present in the product as treating or preventing disease. The words and phrases listed in Appendix 1 of the Guidance note are ones the MHRA has previously decided to be medicinal, in their context. There are around 40 of these phrase examples. In addition to clear cases such as “prevents”, “treats” and “cures”, the list includes for example:

- “Alleviates”
- “Avoids”
- “Clears”
- “Combats”
- “Controls”
- “Counteracts”
- “Eliminates”
- “Fights”
- “Heals”

⁵⁷⁹ Guidance note, paragraphs 15 and 16.

⁵⁸⁰ Guidance note, paragraph 17.

⁵⁸¹ Guidance note, paragraph 18.

“Helps”
“Protects against”
“Remedies”
“Removes”
“Repairs”
“Restores” “Stops” and “Traditionally used for”.

Medicine based on Function

A product may contain nutritional ingredients, and also ingredients having established use as medicine. In these cases, the product may be classified a medicine because of its function. What is important is *the dosage* of the medicinal ingredient. Where there is doubt or dispute whether the recommended dosage level of the active medicinal ingredient is “therapeutic” or not, the MHRA will seek the advice of its medical and pharmaceutical assessors.⁵⁸²

The MHRA states, that many herbs have an established or accepted use as medicines, for example as a bronchodilator (Ephedra), a respiratory stimulant (Lobelia), a sedative (Valerian), a defence against colds and ‘flu (Echinacea), an anti-depressant (St. John’s Wort), a diuretic (Boldo), or an aphrodisiac (Yohimbe bark). *The MHRA will generally consider products containing ingredients like these in therapeutic doses to be medicinal products on the basis that they “may be administered with a view to ... modifying physiological function in human beings”*.⁵⁸³

The MHRA has listed factors that are particularly relevant to deciding whether a product is a medicine under the second part of the definition. These are as follows:

- the pharmacological properties of the ingredient(s) and any significant effect(s) they have on physiological function in humans;
- the product promotional literature, including testimonials and any literature issued by a third party on behalf of the product supplier;
- the product form, (capsule, tablet, etc.) and the way it is to be used;
- the presence of essentially similar licensed or exempt medicines on the UK market.
- any claims, explicit or implicit, which although they may not be claims “for treating or preventing [a specific] disease” could suggest to the average consumer that the product can be taken “with a view to ... restoring, correcting or modifying physiological functions in human beings ...”.⁵⁸⁴

It is interesting that the MHRA uses claims also as indication of the medicinal function. The claims and the function could also be seen as separate issues, based on the two parts of the medicinal product definition. The MHRA sees the two parts of the definition intertwined and weighs presentation and functions as one question. Based on this notion, it seems that if the product combines *somewhat medicinal ingredients* with *somewhat medicinal marketing messages* it is more likely categorized a medicinal product than a product with only one of the above. A strong medicinal function or a strong medicinal claim would be enough.

⁵⁸² Guidance note, paragraph 20.

⁵⁸³ Guidance note, paragraph 21.

⁵⁸⁴ Guidance note, paragraph 23.

It is even more interesting that selling the product in capsule or tablet form is on both lists: *Product form is seen indicative both of medicinal presentation and of medicinal function.* Product form is seen as a message to consumers, the message being ‘this is medicine’, and apparently simultaneously as proof of medicinal functions. However, food supplements are a completely legal and supposedly familiar category to consumers. Food supplements are legally foods: they are merely nutrients in compact form. Food supplements cannot bear medicinal claims.

Herbals

For herbal ingredients, MHRA has provided additional advice. According to MHRA, an increasingly large number of products contain herbal ingredients. Following consultation with a number of UK Trade Associations the Medicines Borderline Section has put together a *guidance sheet on herbal ingredients*, which includes a *list of herbal ingredients and their reported uses*. This list is not binding in that it would resolve the issue of whether a certain herb is a medicine. The status of a product (food vs. drug) is determined on individual basis taking into account all the factors detailed in Guidance Note 8.⁵⁸⁵

The Procedure for Borderline Products

In the UK, also specific *procedural legislation on borderline products* has also been created. Factual grounds for decisions can still be found in the guidance notes and are under MHRA discretion. On 1 March 2000, The Medicines for Human Use (Marketing Etc.) Amendment Regulations 2000 came into force. They improve the way in which the MHRA determines whether a product is a medicinal product. The aim is a more systematic and transparent categorisation procedure (food vs. drug), along with improved compliance and decision enforcement. According to the Amendment Regulations, MHRA will give *full written reasons for its decisions*. There is an *Independent (Advisory) Review Panel* which, on request, will consider written and oral representations against MHRA provisional classification determinations. Guidance on requesting a review of a Provisional Determination issued by the Borderline Section is available. There is now a criminal offence of non-compliance with final MHRA decisions.⁵⁸⁶

⁵⁸⁵ In the UK, there are three different kinds of herbal medicines. In addition to herbal medicinal products requiring authorisation and traditional herbal medicinal products requiring registration, there are exempted herbal medicinal products that can be sold without pre-market control. These exemptions are in section 12 of the UK Medicines Act. These are herbal remedies on open sale, sold with no other name than their herbal constituents and without any written recommendations for use. An herbal remedy exempt from licensing is still subject to other legal requirements for medicines, particularly as to labelling.

⁵⁸⁶ MHRA web page. http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009271&ssTargetNodeId=91.

According to MHRA, this statutory procedure provides *a safe regulatory environment* in which safe and beneficial products are widely available, and illegal products are promptly removed from the market.⁵⁸⁷

The MHRA describes the background of its borderline product legislation on its web page: “The UK was threatened with Infraction Proceedings at the European Court of Justice following the European Commission’s ‘Reasoned Opinion’; early in 1998 that it was not enforcing its decisions consistently and without delay.” The Agency published Consultation proposals in November 1998. Industry and consumer stakeholders were not happy with these first proposals. Based on criticisms, the independent review panel was created, the MHRA was required to give full reasons for its provisional and final decisions, and burden of proof in criminal issues was shifted back to the Agency. These changes to the proposals were presented in July 1999, and all the parties were quite happy with the final legislation package. The process is considered transparent and effective, and the UK satisfies its EC obligations.

The MHRA also has a special determination procedure for cases of emergency:

“In exceptional circumstances, the MHRA is empowered to determine that a product is a relevant medicinal product without following the statutory determination procedure if there are reasons why it would not be appropriate to follow the procedure. Examples are where:

- there is an identifiable risk to public health and /or patient safety; or
- the product is a copy of, or is identical in all material respects to, another relevant medicinal product that has already been the subject of review panel advice.”⁵⁸⁸

UK-type systematic and transparent classification procedures might also be created in other EU Member States. However, the classification decision will in the future likely be transferred under the competence of Community authorities, probably the EMEA. Some Member States might be waiting for this move and therefore not create separate borderline categories and procedures.

3.3 China: Foodstuffs = Medicines?

In the Chinese Medicine Administration Law, pharmaceuticals are defined as follows:

““Pharmaceuticals” are the articles intended for use in the prevention, treatment or diagnosis of human diseases, or intended to effect the purposive regulation of human physiological functions, for which indications or major functions, usage and dosage are prescribed. They include raw traditional Chinese medicinal materials, traditional medicines prepared in

⁵⁸⁷ The MHRA has further issued Guidance on the operation of the statutory process, in particular the Review Panel’s procedures. Trade associations were involved also in drafting this guidance. http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009271&ssTargetNo deId=91.

⁵⁸⁸ Guidance note, paragraph 24.

ready-to-use forms, and other prepared Chinese medicines, medicinal chemicals and their preparations, antibiotics, biochemical medicines, radioactive drugs, serums, vaccines, blood products, diagnostic aids, etc.”⁵⁸⁹

The Chinese definition of medicines is much more detailed than the European definition of ‘medicinal products’. However, in practice the same types of product are covered by both definitions. In China, traditional Chinese medicines are particularly mentioned in the definition. In Europe, the definition of medicines covers traditional herbal medicines. The Chinese want to emphasise the fact that modern and traditional medicines are treated equally. European attitude can be described as allowing the existence of traditional medicine while paying scant attention to it.

A difference between European and Chinese attitude towards foodstuffs and medicines can be detected in the stated task of food law. In China, food is traditionally seen as related to health. Interactions between food and health are obvious to the Chinese. The Chinese Food Hygiene Law was enacted “for the purpose of ensuring food hygiene and preventing food contamination and harmful substances from causing injury to human health in order to safeguard the health of the people *and improve their physical fitness*”. The goal of the new Food Safety Law is more simply stated as “assuring food safety and safeguarding people’s health and life”⁵⁹⁰.

In the Chinese Food Hygiene Law, food was defined as follows:

““Food” means any finished product or raw materials provided for people to eat or drink, as well as any product that has traditionally served as both food and medicament, with the exception of products used solely for medical purposes.”⁵⁹¹

This means that medicine is not permitted in foods. Still, products that have traditionally served as both medicine and food can be used as raw materials, condiments or nutrition fortifiers⁵⁹². The new Food Safety Law distinguishes between foodstuffs and medicines in Article 50: “Medicines can not be added to food, unless the added substance is traditionally considered both food and Chinese medicine.” The catalogue of substances that are traditionally considered both as food and as Chinese medicine will be published by the executive department of health under the State Council. This type of catalogue will offer valuable guidance to Western marketers.

In China, several substances can be used either in foodstuffs or medicines. The major implication of a product being classified as a medicine is that it imposes higher requirements for producers and sellers. For example, manufacturers of medicines must hold a GMP certificate and wholesale and retail enterprises a GSP certificate. This means the categorisation decision (medicine/non-medicine) is as important in China as it is in Europe. However, the classification rules are not clear and the SFDA has not published any guidelines on the subject. Companies are consulting the SFDA on a case-by-case basis.⁵⁹³

The Chinese Advertisement law, Article 19 stipulates: the contents of advertisements for foods, alcoholic drinks or cosmetics must comply with the conditions in the relevant hygiene

⁵⁸⁹ Article 102.

⁵⁹⁰ Article 1.

⁵⁹¹ Article 54.

⁵⁹² Food Hygiene Law, Article 10. “Nutrition fortifier” refers to any natural or artificial food additive belonging to the category of natural nutrients that is put into food to increase its nutritive value. Food Hygiene Law, Article 54.

⁵⁹³ Tsoi 2007.

licence and *no medical jargon or words may be used so as to confuse them with pharmaceuticals*. The rule is very similar to the EU one: foods and medicines must be separated and therefore medicinal claims on foods are prohibited. The Health Food Regulation of 1996 created the health food category between regular foods and medicines. ‘Health food’ is a category suitable for a product that:

- possesses the general nature of food,
- is able to regulate bodily functions of certain consumer groups, but
- is not meant for a therapeutic purpose.

In China, only health foods can bear health claims, and only medicines can bear medicinal claims. Article 11 of the Health Food Regulation separates health foods and medicines from each other: “Any medicinal product approved by the government should not apply for the Certificate of Approval on Health Food”. This way the health food category separates health foods from regular foods at one end, and medicines at the other end. The function and the claim resolve the foodstuff vs. medicine -issue, not the raw material as such. In law, the Chinese seem to have adopted the Western idea of separating between health promotion and disease prevention. The understanding of the roles of foodstuffs and medicines in consumers’ minds is another issue. Products are used by people, laws by businesses.

3.4 Legal Status of Functional Foods

As stated above in chapter 1.2., *‘functional food’ is not a legal term*. The food industry has started to use the term ‘functional’ for food products that in some way promote health or enhance performance. The health-effect is achieved through removal of unhealthy ingredients (like saturated fats), adding of healthy ingredients that already exist in food (like folic acid) or the adding of completely new ingredients.⁵⁹⁴ Functional foods come in many forms: dairy products, beverages, cereals, oils, fats, confectionery, eggs, tomato-based products etc.

The role of functional foods can be understood if we look at different ways to understand health. Using the *medicinal way* to define health, we note health is the absence of disease. A healthy body is like a machine that works well, as opposed to a machine that malfunctions.⁵⁹⁵ In the *humanistic view* to health, health is seen as something more than the absence of disease. The humanistic or holistic view relates health to the ability to function, and the ability to achieve goals that are essential for ones happiness.⁵⁹⁶ The WHO definition of health is extremely humanistic: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”⁵⁹⁷. Functional foods perfectly correspond to the humanistic view of health.

Humanists see health as a continuum or alternatively health and sickness as two different dimensions. The two views are presented in figures A and B.

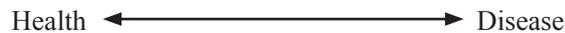
⁵⁹⁴ Elkington – Hailes 1999, 50.

⁵⁹⁵ Medin 2001, 105.

⁵⁹⁶ Medin 2001, 105.

⁵⁹⁷ WHO Constitution, New York 1946.

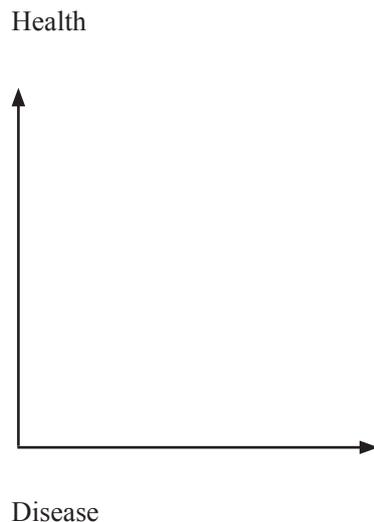
A: Health and Disease as a Continuum:



When health is viewed as a continuum (see figure A), health and sickness can exist simultaneously, and when a person is healthy, he is less sick. When he is sick, he is less healthy.⁵⁹⁸ Closer to the left of the figure, people are in good condition and work freely and they do not have any symptoms relating to weariness or disease. Closer to the right, people have explicit symptoms relating to disease which require treatment. In between, people feel generally weak and can display various symptoms (tiredness, depression, irritability) and these symptoms can affect their ability to manage life.⁵⁹⁹

Bäcklund sees that the role of functional foods is to prevent a person in a state of 'health' from shifting into the state of 'labile health'. The function of medicines would be to prevent a person from moving from the state of 'labile health' into 'disease', or to treat or cure diseases. She views health/disease as a continuum. Certainly she considers functional foods to be aimed at healthy people.⁶⁰⁰

B: Health and Disease as Two Different Dimensions:



When health and sickness are seen as two different dimensions (see figure B), they are not seen as opposites. In this example, it is possible to be very sick and very healthy at the same time, and also not to have any sickness but still not be healthy at all. Health is basically defined by a person's happiness. Some observers think that due to this new thinking there has been a

⁵⁹⁸ Medin 2001, 106.

⁵⁹⁹ Kwak – Jukes, 2000a, 99.

⁶⁰⁰ Bäcklund 1998, 155.

paradigm shift as today the focus of research is usually about what causes well-being, not what causes disease.⁶⁰¹ *Health is a concept in a totally different dimension to diseases.*

These humanist ways to understand health appeal to functional food developers. With the use of functional foods, people can become healthier, even if they cannot directly prevent, treat or cure any disease. Here *experience of health* is decisive⁶⁰².

Making the role of functional foods more complex are the products that are aimed at fighting *a certain disease*. We must draw the line between *disease risk reduction* and *disease prevention* as these two are in the same dimension regardless of how you look at it. The separation between risk reduction and prevention is where food and medicine law ultimately meet.⁶⁰³

In practical linguistics, the difference is not clear. An individual might assume that if she eats healthy food, she will not suffer from a heart attack, which to her means prevention. In *medicine*, the difference has something to do with mathematics. The term *prevention* is used when preventive therapy will produce a result with a substantial degree of statistical certainty, and *risk reduction* claims are based on epidemiological evidence gained from population-based studies.⁶⁰⁴

According to Coppens et al. 2001, there are three types of medicinal disease prevention:

Type 1: prevention of disease occurrence. Key characteristics of this type are that the disease is not (yet) present, and the therapy can prevent the occurrence of the disease with a substantial statistical certainty. This represents the absolute sense of prevention, and is for example the purpose of many vaccines.

Type 2: prevention of episodes of the disease. Key characteristics are that the disease is present, and the therapy decreases the number, duration, or severity of disease episodes with a substantial statistical certainty. This is exemplified by medicines given to patients with chronic diseases, like asthma or epilepsy and should more correctly be considered as part of the management of an existing disease, rather than prevention in the absolute sense.

Type 3: prevention of progression of the patient's underlying disease. Key characteristics are that the disease is present, and that the therapy has been shown to delay the progression of the disease with a substantial statistical certainty. In this case, medicines are given to prevent the more serious consequences of a disease and to hinder its progression rather than to prevent it absolutely. Examples include patients who are either asymptomatic, e.g. lowering blood pressure in hypertensive patients, or symptomatic, e.g. decreasing blood sugar in diabetic patients or treating HIV-positive patients to slow the progression of AIDS.

It is accepted that certain types of foods may contribute towards both type 2 and 3 treatments. These *foods for special medical purposes* are suitable for the dietary management of the particular disease and are regulated at the EU level through Directive 1999/21⁶⁰⁵.

⁶⁰¹ Medin 2001, 106.

⁶⁰² Medin 2001, 106.

⁶⁰³ Besides prevent, foods could also possibly treat or cure diseases. In these cases, these foods would clearly be medicines, e.g. herbal medicinal products, and there is in practice no confusion. Prevention and risk reduction are more difficult to separate, because they both affect something that is not yet there.

⁶⁰⁴ Coppens et al. 2001, 143. The term *prevention* is also used in nutrition, when avoiding deficiencies of essential nutrients. But prevention in the meaning of food and drug law does not cover this kind of malnutrition prevention. The concept in food and drug law is restricted to concern drug effects with the goal to prevent particular diseases.

⁶⁰⁵ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.

Coppens et al. (2001) proposed *a concept of disease risk reduction*. The key characteristics of disease risk reduction are:

- The disease is not present.
- The cause of the disease is multi-factorial, including dietary, behavioural, environmental, and genetic factors.
- Modification of certain dietary components, alone, cannot ensure that the disease will not develop, since it does not affect the other factors but, nevertheless, it may help significantly to reduce the likelihood of getting a disease.⁶⁰⁶

In the current European legal framework for foods and medicines, there are still no definitions for prevention and risk reduction. There is, however, a definition of “reduction of disease risk claim”: “any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease”⁶⁰⁷. This means that according to European law, reducing disease risk means *reducing a risk factor* in the development of a disease. The concept of disease risk reduction takes into account the complexity and the multi-factor nature of diseases as well as the complexity of diet.⁶⁰⁸ This fits to Coppens’ et al. idea that a nutrient can significantly lower one risk factor in a multi-factorial disease.

Based on the previous chapters, a functional food could legally be judged as a medicinal product, if it is *presented* for disease *prevention*.⁶⁰⁹ In this thesis, ‘functional food’ is used as a practical term to describe the products we are interested in. These are products with health effects. Legal requirements for so-called functional foods are analysed regarding A) safety and B) efficacy/marketing. This means we end up with *novel food legislation and health claim legislation*, where the term ‘functional food’ has no relevance.

In one Finnish study of 1999⁶¹⁰, consumers found it curious that there was no legal definition of functional foods. Because there has been a lot of public attention surrounding functional foods, some people might have thought that functional foods were a product category with an official definition. This was not the case so many consumers suspected that the concept was just another marketing trick to hoax consumers.⁶¹¹ A legal definition of ‘functional food’ might have thus strengthened the whole concept of functional foods. Instead of defining the term ‘functional food’, the Europeans have taken the approach to precisely regulate nutrition and health claims. ‘Functional food’ can be understood as just one type of marketing claim. The Chinese, on the contrary, have created a separate health food category for products on which health claims are allowed.

The Chinese Health Food Regulation defines health foods as food products proven to have specific health functions, designed for a specific population to consume, but which are not for the purpose of disease treatment. Neither in the EU nor in China is it conclusive whether it is possible to bite, chew, taste or swallow the substance. *The form of the object does not*

⁶⁰⁶ Coppens et al. 2001, 144.

⁶⁰⁷ Nutritional and Health Claim Regulation Article 2(2) (6).

⁶⁰⁸ Council of Europe guidelines, 17.

⁶⁰⁹ Coppens et al. 2001, 143.

⁶¹⁰ Niva – Jauho 1999.

⁶¹¹ Niva – Jauho 1999, 46.

determine whether it is a food or a medicine. This is how the law sees it, and this is also how consumers see it. Consumers often do not see the two as legal concepts, even though they are widely affected by their legal definitions.

The decision on whether the product is a foodstuff or a medicine is important, because there are separate pre-market procedures for foodstuffs and medicines with separate laws and scientific requirements. The functional difference between a foodstuff and a medicine is simultaneously a difference in the marketing claim. The function, the product efficacy, is the marketing message. As stated above, one cannot make medicinal claims on foods.

It is similarly true that: *one cannot make health claims on medicinal products.* The Finnish report on Article 13 health claims contains various claims on products that are considered medicinal according to the Medicines Agency. This is because they contain ingredients listed in the Pharmacopoeias and/or prevent, treat or cure diseases according to scientific studies.⁶¹² The operators do not see their products as medicines, but sell or plan to sell them as foods using health claims. However, this is not possible if the product has medicinal functions. After the categorisation decision (foodstuff/medicine), one cannot choose between a health claim and a medicinal claim.

As Tuori points out, legal concepts are not innocent: they confer rights and obligations. Concepts frame a legal issue and place it in a certain normative context, at the same time limiting the possible solutions to regulatory issues.⁶¹³ This is the case with functional foods and the issue of how to regulate them. The concepts of ‘food’ and ‘medicine’ are part of the legal culture, and limit our ability to solve the questions of safety and efficacy of functional foods. Therefore, the concepts themselves need to be critically examined.

Legal reasoning and justification can adhere to sources of law, legal concepts, legal principles, or ideological choices. These can be seen as levels, where sources of law form the ground level as they are most attached to positive law, and where different types of arguments (for example: linguistic, systemic, teleological, moral) are relevant and typical on different levels of justification.⁶¹⁴ We are of the view that all argument types are relevant when legally defining the concepts of foodstuff and medicine. Linguistically, legal definitions create meanings and legal categories that are not the same as in everyday language. Coherence naturally requires the meaning of the concepts to be the same across all legislation in a certain legal system. This is the systemic argument. However, *the legal concepts of foodstuff and medicine as against each other* will change through time, based on practical, economical, and moral reasons.

Grounds for the strict separation of foods and medicines appear to have changed, which allows us to consider changes in the legal concepts. *On legislators’ wish, the two concepts could be replaced by three concepts, one concept, or no legal concept at all.* In the last case, we would focus on safety and efficacy of for example berries, herbs, and chemical substances without the need to categorise first. The two legal concepts originally evolved in different circumstances compared to the present. In times of first food laws (for example in Finland in the 1940s), health-effects of foods were not widely established, and there was no functional food business. The concepts of food and medicine are also currently used in Chinese law, even

⁶¹² Report on health claims used in marketing of foodstuffs in Finland, page 25.

⁶¹³ Tuori 2000, 310.

⁶¹⁴ See Raitio 2006, 30-35, on justification levels and argument types.

though Chinese tradition clearly speaks against the strict separation. The concepts of food and medicine came to China in the 1980s from Western laws.

Both in the EU and in China, there are products that can be sold either as food or medicine, depending on whether they are used by and marketed to healthy vs. sick people as is the case with garlic, for example. Still, there are the two legal categories that marketers and the administrators must recognise. *One product cannot be a food and a medicine at the same time, two of the same products can.* The rationality of this deserves critique.



4 SAFETY OF FOODSTUFFS AND MEDICINES

Safety of foodstuffs and medicines is a highly important issue to consumers. New ingredients in particular in functional foods, herbal medicines, etc. might be hazardous to health. It is possible to overdose on even healthy products or ingredients.

4.1 General Product Safety

4.1.1 Europe

In the EU, directive 2001/95/EC⁶¹⁵ governs general product safety. The directive sets responsibilities on both the producers and distributors of products. They must be aware of the qualities and use of the products, give adequate information to consumers, and take dangerous products off the market.⁶¹⁶ This means they must themselves be active in ensuring product safety. The general product directive applies to products that are:

- intended for consumers or likely to be used by consumers, and
- supplied in the course of a commercial activity⁶¹⁷.

Among other consumer products, the directive applies to foodstuffs, medicines, and everything in between, including functional foods. However, the general product safety directive applies only where there are no specific provisions with the same objective in rules of Community law. Where products are subject to *specific safety requirements* imposed by Community legislation, the general product safety directive applies only to the aspects and risks not covered by those requirements.⁶¹⁸

⁶¹⁵ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001. Applicable as from 15 January 2004.

⁶¹⁶ Article 5 of the directive.

⁶¹⁷ Article 2 (a). The exact definition of “product” is “any product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned”.

⁶¹⁸ Article 1(2).

Requirements for safe foodstuffs and medicines are usually to be found in EU food and medicine law. However, the general product safety directive might also still have its role regarding these products. According to preamble 5 of the directive, it is very difficult to adopt Community legislation for every product which exists or which may be developed. That is why “there is a need for a broad-based, legislative framework of a horizontal nature to deal with such products, and also to cover lacunae, *in particular pending revision of the existing specific legislation, and to complement provisions in existing or forthcoming specific legislation*, in particular with a view to ensuring a high level of protection of safety and health of consumers, as required by Article 95 of the Treaty”⁶¹⁹.

According to Article 3(1) of the general product safety directive, “producers shall be obliged to place only safe products on the market”. In the absence of a *specific EU law* governing the safety of a product, the product shall be deemed safe if it conforms to *national law of the Member State* in whose territory the product is marketed⁶²⁰. If there is no Member State law, safety assessment is based on European and member state standards, Commission recommendations, product safety codes of good practice, the state of the art and technology, and reasonable consumer expectations⁶²¹.

There is a safeguard clause included in the directive: even if the product complies with all of the above-mentioned norms and criteria, the competent authorities of the Member States can still restrict marketing of the product, or require its withdrawal from the market. This is if there is evidence that, despite such conformity to norms, the product is dangerous.⁶²² In general marketing law, a safeguard clause like this is not included because it leads to restrictions on free movement of goods, see chapter 5 below.

4.1.2 China

In China, general product safety is regulated by the Consumer Protection Law (1993) and by the Product Quality Law (1993, amended 2000). The Chinese consumer protection law can be seen as instructions for three different actors: consumers themselves, marketers of consumer products, and control authorities. According to Article 7 of the Consumer Protection Law, the consumer has the right to purchase only safe products:

“In purchasing and utilising commodities or accepting services, the consumers enjoy the inviolable right of the personal and property safety. The consumers have the right to demand the commodities or services provided by the operators agree with the requirements of ensuring the personal and property safety.”

Article 18 states the same from the viewpoint of the sellers:

“The operators shall guarantee that the commodities or services they provide agree with the requirements of ensuring the personal and property safety. In regard to the commodities or

⁶¹⁹ Preamble 5 of the directive.

⁶²⁰ Article 3(2) of the directive.

⁶²¹ Article 3(3) of the directive.

⁶²² Article 3(4) of the directive. The Member States must inform the Commission of the restrictive measure taken. The Commission communicates the information to other Member States unless the Commission decides that the measure does not conform to Community law. Article 11 of the directive.

services which pose potential hazard to personal and property safety, the operators shall make true to fact descriptions and clear warning to the consumers, specify and label the correct method in utilising the commodities or accepting services and the method of preventing the occurrence of injury and damage. When the operators discover that the commodities or services they provide cause serious defects and might cause injury or damage to the personal and property safety even under correct utilisation of the commodities and acceptance of the services, the operators shall promptly report to relevant administrative departments and inform the consumers and take measures to prevent the occurrence of such injury and damage.”

Article 27 states the same one more time, from the viewpoint of the governments:

“People’s governments at all levels shall strengthen their supervision, prevent the occurrence of the act which hazards the personal and property safety of the consumers, and timely put an end to the act which hazards the personal and property safety of the consumers.”

The Chinese Product Quality Law is more specific when it comes to product safety. Chapter II on Product Quality Supervision states the following:

“Industrial products which might endanger the health and personal or property safety must comply with the national or sector standards for safeguarding the health and personal or property safety; and in case of absence of such national or sector standards, they must comply with the requirements for safeguarding the health and personal or property safety.

It is forbidden to produce or to sell industrial products which fail to comply with the standards and requirements for safeguarding the health and personal or property safety. The concrete measures therefore are provided by the State Council.”⁶²³

The producer and seller’s liability is stated in chapter III:

“Producers shall be liable for the quality of products they produce. The quality of a product shall satisfy the following requirements:

1. *being free from unreasonable dangers to the personal or property safety*, and conforming to the national or sector standards for safeguarding the health and personal or property safety if such standards are available;

...”

Also the product labelling is important regarding product safety: there must be a warning mark or warning explanatory words in Chinese language if a product, due to improper use, might cause damage to the product itself or might endanger the personal or property safety.⁶²⁴

Consumer protection laws in China have been accused of being vague and unintelligible. Article 7 of the Consumer Protection Law calls on companies to maintain standards of safety defined as “contemporary technical and professional standards of...the sold goods launched into the market.” This can be interpreted to mean that safety standards fluctuate with the shifts of the market, and that companies are only expected to maintain the standards currently established by other companies. Article 8 states that businesses cannot be punished for falling behind raised standards established by goods entering the market at a later time.

⁶²³ Article 13.

⁶²⁴ Product Quality Law, Article 27(5).

4.2 Food Safety

4.2.1 EU

4.2.1.1 General Rules on Food Safety

According to EU General Food Regulation, food shall not be placed on the market if it is unsafe⁶²⁵. Food shall be deemed to be unsafe if it is considered to be:

- (a) injurious to health;
- (b) unfit for human consumption.⁶²⁶

Article 14(3) clarifies the evaluation of safety:

”In determining whether any food is unsafe, regard shall be had:

- (a) to the *normal conditions of use* of the food by the consumer and at each stage of production, processing and distribution, and
- (b) to the *information* provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.”

Article 14(4) takes into account also long-term and cumulative effects, plus particular consumer groups:

“In determining whether any food is injurious to health, regard shall be had:

- a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on *subsequent generations*;
- b) to the probable *cumulative toxic effects*;
- c) to the particular health sensitivities of a *specific category of consumers* where the food is intended for that category of consumers.”

Article 14(5) concerns mainly food going bad under time and external conditions: “In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.”

Article 14(6) takes the precautionary principle seriously: “Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.”

⁶²⁵ Article 14(1).

⁶²⁶ Article 14(2).

Articles 14(7) to 14(9) clarify the role of more specific Community or Member State safety standards:

- “7. Food that complies with *specific Community provisions* governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.
9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the *specific provisions of national food law* of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.”

4.2.1.2 *Biological Safety of Food: Hygiene*

EU legislation on biological safety of foods has been revised as of 2006 by the so called “hygiene package”. This legislative package includes:

- Regulation 852/2004/EC on *the hygiene of foodstuffs*
- Regulation 853/2004/EC on specific hygiene rules for *food of animal origin*, and
- Regulation 854/2004/EC laying down specific rules for the organisation of *official controls on products of animal origin*⁶²⁷.

The new regulations merge and harmonise hygiene requirements previously contained in several separate directives. The goal of new hygiene legislation is to make a single, transparent hygiene policy applicable to all food and all food operators in the food chain. This would enable the EU to manage food safety and future food crises.⁶²⁸

The Annexes of Regulation 852/2004/EC contain hygiene rules applicable to primary production (Annex I), and to other food business operators (Annex II). The hygiene rules in Annex II include requirements for rooms where foodstuffs are prepared, treated or processed, requirements for movable and/or temporary premises, transport, equipment, food waste, water supply, personal hygiene, hygiene of the foodstuffs themselves, wrapping and packaging of foodstuffs, heat treatment, and training.

Annex III of Regulation 853/2004/EC contains hygiene rules for various foodstuffs or animal origin, which were previously scattered in different Directives. There are rules on meat, fishery products, eggs, milk, frog’s legs and snails, bivalve molluscs, and processed

⁶²⁷ All of these were enacted on 21st April 2004, and came into force in the beginning of 2006. The package includes also Directive 2004/41/EC repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC, 21 April 2004.

⁶²⁸ European Commission web page. http://ec.europa.eu/food/food/biosafety/hygienelegislation/index_en.htm.

products. The rules are quite exact, of the type: “Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products”⁶²⁹.

To facilitate the application of the new hygiene rules, the Commission has enacted a set of implementing measures, the most important being the Commission Regulation 2073/2005/EC which sets down microbiological criteria for foodstuffs. The Commission has also enacted various transitional rules that help operators adjust their businesses to fit the new regime⁶³⁰.

4.2.1.3 Chemical Safety of Food

Chemical safety of foodstuffs is in Europe guaranteed by regulating:

- food additives,
- food flavourings,
- contaminants,
- residues and
- food contact materials.

The European Commission has in 2008 adopted a legislative package, which updates rules for additives⁶³¹ and flavourings⁶³², and harmonises EU legislation on *food enzymes*⁶³³ for the first time. A common approval procedure for food additives, flavourings and food enzymes was created⁶³⁴. EFSA has an integral role in assessing new substances.⁶³⁵ Only additives, flavouring, and food enzymes that are on the EU lists can be used, and only under the conditions mentioned in those lists. Often, they can be used in limited quantities⁶³⁶.

⁶²⁹ Regulation 853/2004/EC, Annex III, Section VIII, Chapter III. A(4).

⁶³⁰ European Commission web page. http://ec.europa.eu/food/food/biosafety/hygienelegislation/legisl_en.htm.

⁶³¹ Regulation (EC) No 1333/2008 on food additives. The regulation, except transitional provisions, will apply by 20 January 2010. Additives that are permitted under the old directives 94/35/EC, 94/36/EC and 95/2/EC will be put Community list of food additives. Their conditions of use are first to be reviewed, and this review should be completed by January 2011.

⁶³² Regulation (EC) No 1334/2008 on flavouring and certain food ingredients with flavouring properties amending Council Regulation (EEC) no 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. The regulation will apply on 20 January 2010. However, the old Regulation 2232/96/EC will continue to apply until the date of application of the Community list of flavourings.

⁶³³ Regulation (EC) No 1332/2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97. The regulation applies from 20 January 2009, except labelling provisions from 20 January 2010. National provisions apply in the Member States until the adoption of the Community list of enzymes applies.

⁶³⁴ Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

⁶³⁵ See Luetzow 2006.

⁶³⁶ European Commission web page. http://ec.europa.eu/food/food/chemicalsafety/additives/comm_legisl_en.htm.

Additives are substances added to foods for some technological purpose, for example to preserve, to sweeten or to colour⁶³⁷. *Flavourings*⁶³⁸ are substances used to give taste and/or odour to food. *Enzymes* are added to perform a technological function for example in the manufacture, transport, or storage of a food⁶³⁹.

Additive, flavouring, and enzyme rules do not apply to substances added to foodstuffs as nutrients, such as vitamins or minerals. The enzyme Regulation does not extend to enzymes for nutritional or digestive purposes⁶⁴⁰. These are regulated under the rules of food fortification. See below.

Contaminants are substances that have not been intentionally added to food. Foodstuffs may be contaminated by environmental contamination, or in various stages of the food chain, for example production, packaging, or transport. The aim of EU legislation is to minimise contaminants in foodstuffs. *Basic principles* of EU legislation on contaminants in food are in Council Regulation 315/93/EEC. *Maximum levels* for certain contaminants in certain foods are set in Commission Regulation 1881/2006/EC⁶⁴¹. The following contaminants are included: nitrate, mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, T²-2 and HT-2-toxin), metals (lead, cadmium, mercury, inorganic tin), 3-MCPD, dioxins and PCBs, and polycyclic aromatic hydrocarbons (PAH).⁶⁴²

Residues are chemicals that are intentionally used in some part of the food chain but which are not intended to be present in foods. Animals are treated with medicines, which leads to residues of these medicines in meat, milk and eggs⁶⁴³. Plants are fertilised and treated with pesticides. Veterinary medicines and their maximum residue levels are evaluated according to regulation 2377/90/EC. The basic directive setting maximum residue levels for pesticides (90/642/EEC) has been amended dozens of times.

Food contact materials are materials and articles intended to come into contact with foodstuffs⁶⁴⁴. This includes food packaging but also knives and forks, plates and glasses, bowls and jars, blenders and mixers. The framework regulation 1935/2004/EC sets up general requirements for all food contact materials. Specific directives exist for ceramics, regenerated

⁶³⁷ The full definition of “additive” is the following: “any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”. Regulation 1333/2008/EC, Article 3(2)(a). In addition, there is a long list of substances that are not considered additives.

⁶³⁸ “Flavourings” are “products: (i) not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste; (ii) made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof”. There are several additional definitions in the Regulations.

⁶³⁹ The full definition of “food enzyme” is the following: “a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms:

- (i) containing one or more enzymes capable of catalyzing a specific biochemical reaction; and
- (ii) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods”. Regulation 1332/2008/EC, Article 3(2)(a).

⁶⁴⁰ Regulation 1332/2008/EC, preamble 4.

⁶⁴¹ This Regulation entered into force on 1 March 2007.

⁶⁴² Investigations are ongoing on acryl amide, organotins, furan, and ethyl carbamate.

⁶⁴³ European Commission web page. http://ec.europa.eu/food/food/chemicalsafety/residues/index_en.htm.

⁶⁴⁴ European Commission web page. http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm.

cellulose film and plastics. Food contact materials must be safe and not transfer their components into the foodstuff in unacceptable quantities⁶⁴⁵. Intelligent and active packaging is allowed by the new Regulation. If an active packaging changes the composition or sensory properties of the product, the changes are evaluated according to rules on additives⁶⁴⁶.

4.2.1.4 Safety of Dietetic Foods

Foodstuffs intended to satisfy particular nutritional requirements of specific groups of the population are called “*foods for particular nutritional uses*”, “*dietetic foods*” or “*dietary foods*”. Sometimes they have also been referred to as “PARNUTS” foods. Council directive 89/398/EEC⁶⁴⁷ is the framework directive on dietetic foods.

Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability. A particular nutritional use must fulfil the particular nutritional requirements:

- of certain categories of persons whose digestive processes or metabolism are disturbed; or
- of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or
- of infants or young children in good health.⁶⁴⁸

Consideration is given to whether the foods in question are clearly distinguishable for their claimed nutritional purposes from ordinary foods. They should be consumed by specific group of population for a particular physical or physiological condition and/or specific disease or disorder, and they should be significantly different from ordinary foods in composition.⁶⁴⁹ Examples of dietetic foods are children’s foods, gluten-free foods (for people with celiac disease), low-lactose and lactose free products (for people with lactose intolerance), low-sodium products, clinical nutrition (medical foods), weight-loss products, and sports nutrition. The marketer decides whether to sell the product as a dietetic food.⁶⁵⁰ Below in chapter 5 we will discuss this marketing decision and alternatives to marketing the product as dietetic food.

The framework directive sets out a framework of rules for the composition, marketing and labelling requirements of dietetic foods, including measures to ensure the appropriate use of such foods and to *exclude any risk to human health*. However, the framework directive does not entail exact safety criteria. Actual compositional requirements, hygiene requirements, lists of additives, purity criteria, etc. are to be found in *separate directives* for the following foods:

⁶⁴⁵ European Commission web page. http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm.

⁶⁴⁶ Regulation 1935/2002/EC, Article 4(1).

⁶⁴⁷ Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (89/398/EEC).

⁶⁴⁸ Article 1.2. of the directive.

⁶⁴⁹ Kwak – Jukes 2000b, 111.

⁶⁵⁰ Food Safety Agency web page. http://www.evira.fi/portal/fi/elintarvikkeet/valvonta_ja_yritt_j_t/erityisruokavaliovalmisteet/.

- infant formula and follow-on formula⁶⁵¹,
- processed cereal-based foods and baby foods (weaning foods)⁶⁵²,
- foods intended for use in energy-restricted diets for weight reduction⁶⁵³, and
- foods for special medical purposes⁶⁵⁴.

The nutritional substances that can be added to dietetic foods are controlled either through positive lists included in the specific directives or by Commission Directive 2001/15/EC⁶⁵⁵, the Annex of which has been amended⁶⁵⁶ to include additional substances⁶⁵⁷. The Annex has 5 pages and includes vitamins, minerals, amino acids, carnitine and taurine, nucleotides, and choline and inositol.⁶⁵⁸ The choice of substances should be based primarily on their safety, and the permission to use certain substances does not mean that their addition is necessary or desirable⁶⁵⁹.

Rules on *infant formula and follow-on formula* were recently revised by Directive 2006/141/EC⁶⁶⁰. These are products designed to satisfy the specific nutritional requirements of healthy infants and young children. Infant formulas are used as sole nutrition, and follow-on formula as the primary liquid element in the diet as the infant grows and starts to eat solid food. *Processed cereal based foods and other baby foods*, regulated by Directive 2006/125/EC⁶⁶¹, are intended for use by infants while they are being weaned, and by young children as a supplement to their diet and/or for their progressive adaptation to ordinary food⁶⁶². “Infant” means a baby under the age of 1, and “young child” a child between the ages of 1 and 3.

Weight-loss-foods are regulated by directive 96/8/EC⁶⁶³. The Directive lays down compositional criteria for weight-control products that are either A) total daily diet replacements

⁶⁵¹ Commission Directive 2006/141/EC of 22 December 2006 on infant formula and follow-up formula and amending Directive 1999/21/EC.

⁶⁵² Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children.

⁶⁵³ Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction.

⁶⁵⁴ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.

⁶⁵⁵ Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

⁶⁵⁶ By Commission Directive 2004/5/EC of 20 January 2004 and by Commission Directive 2006/34/EC.

⁶⁵⁷ Addition of substances into infant formula, follow-up formula, processed cereal-based foods and baby foods intended for infants and young children is regulated in separate directives covering these dietetic foods. Addition of substances into medical foods is regulated by both the separate directive (vitamins and minerals) and the general directive (amino acids). Addition of substances into weight-loss foods is covered by directive 2001/15/EC.

⁶⁵⁸ Most of allowed substances can be used in all dietary foods, but some amino acids can be used only in medical foods.

⁶⁵⁹ Directive 2001/15/EC, preamble 4.

⁶⁶⁰ Commission Directive 2006/141/EC of 22 December 2006 on infant formula and follow-up formula and amending Directive 1999/21/EC.

⁶⁶¹ Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version).

⁶⁶² Article 1(2).

⁶⁶³ Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction

or B) individual meal replacements⁶⁶⁴. The compositional criteria include energy, protein quantity and quality, fat quantity and type, minimum and maximum levels for dietary fibre, and minimum levels for certain vitamins and minerals.

Medical foods (dietary foods for special medical purposes) are foods that are specifically formulated, processed and intended for the dietary management of diseases, disorders or medical conditions of individuals who are being treated *under medical supervision*. These foods are covered by Directive 1999/21/EC⁶⁶⁵. Medical foods are intended for the feeding of people whose nutritional requirements cannot be met by normal foods or other dietary foods⁶⁶⁶. *This means medical foods are not a suitable legal category for functional foods*. Medical foods in practice are liquids or powders that contain carbohydrates, fat etc., for example for cancer patients.

Medical foods may be marketed within the Community only if they comply with the rules laid down in the Directive. The formulation of medical foods shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe, beneficial, and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data, and the foods must comply with the compositional criteria specified in the Annex of the Directive.⁶⁶⁷

A separate directive does still not regulate foods for athletes, even though they are included in the framework directive list of groups of dietary foods for which specific rules shall be set out. The directive has been "looming in the background" for a long time, as manufacturers were already in the beginning on 2005 worried about its possible restrictive and negative effects⁶⁶⁸.

In the White Paper on Food Safety, the Commission announced the intention to introduce a specific Directive on foods intended to meet the needs resulting from intense muscular effort. There is a report of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen⁶⁶⁹, and an Opinion on safety aspects of creatine supplementation⁶⁷⁰. The Directive was circulating in draft form in 2004 and 2005. According to "Consumers for Health Choice", the publication of the proposal has been delayed by the successful campaign of the European Specialist Sports

⁶⁶⁴ Article 1(2) of the Directive.

⁶⁶⁵ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.

⁶⁶⁶ More precisely: "patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two". Article 1(2)(b) of the directive.

⁶⁶⁷ Art. 2-3.

⁶⁶⁸ Callard 2005. Sports nutrition is becoming more mainstream as more people are working out. Sports nutrition covers product areas such as energy and endurance, recovery and refuelling, and rehydration. Products are for example in the form of bars (high-complex carbohydrate and high-protein) or drinks (isotonic/hypotonic). Also caffeine and creatine are used in products.

⁶⁶⁹ Adopted by the SCF on 22 June 2000, corrected on 28 February 2001.

⁶⁷⁰ Adopted by the Scientific Committee on Food on 7 September 2000.

Nutrition Alliance (ESSNA)⁶⁷¹. The European and American supplement industries strongly oppose legislation on their products. They are mainly concerned about bans on several ingredients and stronger, “higher-potency” products.

The framework directive also requires the Commission to report on the desirability of special legislation on foods intended for people suffering from *diabetes*. According to the Commission, “initial consultations with interested parties have been held on this issue”. The Commission intends to report on the desirability of special provisions for foods for diabetics. The Commission also intends to put forward legislative proposals but the timing of this is unclear⁶⁷².

Dietetic foods differ from normal foods in that some of them include a *pre-market notification* system. EU Member States must ensure that dietetic foods comply with the requirements set by the directives. They can use pre-market notification to achieve this goal. In Finland, pre-market notification is *required* for the following products:

- low lactose or lactose free dairy products,
- low sodium products, including low sodium or no sodium table salts,
- gluten free foods,
- some weight loss products (others than meal or diet replacements),
- some medical foods⁶⁷³, and
- other foods complying with the definition of dietetic food, for example foods for people with high cholesterol.⁶⁷⁴

In Finland, pre-market notification is *not required* for the following dietetic foods:

- infant formula and children’s foods
- some weight loss products (meal or diet replacements⁶⁷⁵)
- some medical foods
- sports nutrition
- foods for diabetics.⁶⁷⁶

⁶⁷¹ Consumers for Health Choice describes itself as an exceptionally successful lobby. They are in practice lobbying for Health Product Manufacturers. Consumers for Health Choice web page. http://www.consumersforhealthchoice.com/index.php?option=com_content&task=view&id=35&Itemid=61.

⁶⁷² European Commission web page. http://ec.europa.eu/food/food/labellingnutrition/diabetic/index_en.htm.

⁶⁷³ Medical foods must be notified if they are manufactured in Finland or outside European Economic Area, and imported to Finland for the first time. This means that if medical foods are already on the market in some other European country, they need not be notified when imported to Finland.

⁶⁷⁴ Food Safety Authority web page. http://www.evira.fi/portal/fi/elintarvikkeet/valvonta_ja_yritt_j_t/erityisruokavaliovalmisteet/ilmoitus_erityisruokavaliovalmisteen_markkinoille_saattamisesta/.

⁶⁷⁵ As compositional criteria for meal or diet replacements are given by Directive 96/8/EC, they need not case-by-case pre-market control.

⁶⁷⁶ Food Safety Authority web page. http://www.evira.fi/portal/fi/elintarvikkeet/valvonta_ja_yritt_j_t/erityisruokavaliovalmisteet/ilmoitus_erityisruokavaliovalmisteen_markkinoille_saattamisesta/.

4.2.1.5 Safety of Food Supplements

Food supplements, regulated by Directive 2002/46/EC⁶⁷⁷, are concentrated sources of nutrients or other substances with a *nutritional or physiological effect*, whose purpose is to supplement the intake of nutrients in the normal diet. They are foods marketed in *dose form*, i.e. as pills, tablets, capsules, liquids in measured doses etc.⁶⁷⁸ Products typically contain vitamins, minerals, amino acids, fibre, etc. Food supplements have *no relevant energy content*. Food supplements and dietetic foods are sometimes used for similar purposes, such as for weight loss or as sports nutrition. What often separates dietetic foods and food supplements is their energy content.⁶⁷⁹ Dietetic foods replace meals and diets; food supplements do not. Formulas that contain pure carbohydrates or proteins are dietetic foods.⁶⁸⁰

Food supplements are distinguishable from functional foods because of their form. The basic requirement for functional foods, as defined above in chapter 1.3., is that they can be consumed as a part of total diet and in the form of ordinary foods. From their appearance, food supplements are more like medicines. Medicinal claims are not, however, permitted in food supplements, either. This is because the definition of food supplements does not allow medical uses.

Safety of food supplements is regulated in the EU by a list of permitted substances. Annex II of Directive 2002/46/EC is a list of permitted vitamin or mineral preparations that may be added for specific nutritional purposes in food supplements. Commission Directive 2006/37/EC to include additional substances has amended it. The trade of products containing vitamins and minerals not listed in Annex II has been prohibited since August 2005⁶⁸¹. The European Food Safety Agency (EFSA) may consider vitamin and mineral substances for inclusion in the lists following the evaluation of an appropriate scientific dossier concerning the safety and bioavailability of the individual substance.⁶⁸² Pre-market notification applies to production or marketing of food supplements, if a Member State requires it. For example, Finland requires pre-market notification.

As far as vitamins and minerals are concerned, the Directive does two things. First, it establishes lists of the vitamins and minerals and their forms that can be used in the manufacture of food supplements. Second, it foresees the setting of *maximum levels* for vitamins and minerals in food supplements. These levels will be established in the next few years on the basis of the advice the Commissions will receive from the scientists. The setting of maximum

⁶⁷⁷ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

⁶⁷⁸ More precisely, “food supplements” means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. Article 1(a).

⁶⁷⁹ The Finnish Food Safety Agency considers the energy content irrelevant, if the maximum dosage does not exceed 200 kJ per day. Finnish Food Safety Agency guidelines on food supplements, updated December 2006, page 5.

⁶⁸⁰ Finnish Food Safety Agency guidelines on food supplements, updated December 2006, page 22.

⁶⁸¹ Under certain conditions, Member States may provide derogations until the end 2009, for vitamins and minerals and their forms not included in the Directive.

⁶⁸² European Commission web page. http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm.

limits is complicated, as the total intake of nutrients from all sources must be taken into consideration.

In 2006, the Commission issued a Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs⁶⁸³. The Commission received several comments⁶⁸⁴, and the Commissioner Kyprianou gave a collective answer to these comments⁶⁸⁵. In July 2007, the European Commission issued an “Orientation Paper” to selected parties including the Member States. Legislative proposals were awaited - or feared - in 2008.

The maximum amounts of vitamins and minerals will probably be set both for fortified foods as well as for food supplements⁶⁸⁶. Stakeholders, such as the Finnish government, supported this approach presented in the Discussion paper. At the end of 2007, the European Commission was “finalising approaches that allow the determination of maximum levels of vitamins and minerals for both food supplements and fortified foods”⁶⁸⁷. Some health product manufacturers were concerned about the effects of the future legislation⁶⁸⁸. Others welcomed it and referred to it as a legally and scientifically “balanced” approach⁶⁸⁹. It is possible that maximum levels will be lower for fortified foods than for food supplements, as the risks with fortified foods are more difficult for the consumer to assess⁶⁹⁰.

Besides the maximum and minimum levels of vitamins and minerals, another important question related to food supplements remains to be answered. By July 2007, the European Commission was to present a report on the advisability to include *additional categories of substances, besides vitamins and minerals*, into the legal provisions for food supplements⁶⁹¹. This would mean harmonising the rules on food supplements consisting of botanicals and herbals, amino acids, and fatty acids.

Other substances in food supplements besides vitamins and minerals are at the moment regulated on national level⁶⁹². In Finland, the rules are given in “the guide on food supplements” by the Food Safety Authority⁶⁹³. Above we have discussed problems with soft law, of which the food supplement guide is a good example. Important issues are resolved by a detailed document which is not binding and not available in languages other than Finnish.

⁶⁸³ European Commission web page. http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf.

⁶⁸⁴ European Commission web page. http://ec.europa.eu/food/food/labellingnutrition/supplements/resp_discus_paper_amount_vitamins.htm.

⁶⁸⁵ January 2007.

⁶⁸⁶ Fortified foods will be discussed in the next chapter.

⁶⁸⁷ Alliance for Natural Health. ANH Position Paper: Proposed European Model for MRLs not Fit for Purpose. 24 October 2007. Page 2.

⁶⁸⁸ Alliance for Natural Health. ANH Position Paper: Proposed European Model for MRLs not Fit for Purpose. 24 October 2007.

⁶⁸⁹ European Responsible Nutrition Alliance (ERNA) according to EAS news.

⁶⁹⁰ Opinion of the Finnish Ministry of Trade and Industry. 29 September 2006. Available at European Commission web page: http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/finland_en.pdf.

⁶⁹¹ This is required by Article 4(8) of the Directive: “Not later than 12 July 2007, the Commission shall submit to the European Parliament and the Council a report on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of nutrients or of substances with a nutritional or physiological effect other than those referred to in paragraph 1, accompanied by any proposals for amendment to this Directive which the Commission deems necessary.” This means other nutrients than vitamins or minerals. The Commission has apparently failed to present the report in time.

⁶⁹² Silano et al. 2004, 115.

⁶⁹³ Available at http://www.palvelu.fi/evi/files/55_519_331.pdf.

4.2.1.6 Safety of Fortified Foods

According to the General Principles of the Codex for the Addition of Essential Nutrients for Foods, *fortification* or enrichment means:

- the addition of one or more essential nutrients to a food,
- whether or not it is normally contained in the food,
- for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients,
- in the population or specific population groups.

The fortification or enrichment of various foods is conducted for the purpose of nutritional need or for a commercial purpose. Taking into account that functional foods are often made by adding some functional substances, the law on enriched or fortified foods has a significant implication for functional foods⁶⁹⁴. There is a wide range of nutrients and other ingredients that might be used in food manufacturing, including vitamins, amino acids, essential fatty acids, fibre, various plants and herbal extracts. The substances used in fortified foods are thus practically the same as the substances used in food supplements.

Regulation 1925/2006/EC⁶⁹⁵ harmonises the provisions on the addition of vitamins and minerals substances to foods⁶⁹⁶. Since January 2007, only certain vitamins and minerals can be added, and only in certain forms⁶⁹⁷. Annex I of the Regulation lists vitamins and minerals which may be added to foods. Annex II lists the sources of vitamins and minerals which may be added to foods. There are soft law guidelines on how to have substances added to these lists⁶⁹⁸. Annex III lists substances whose use in foods is prohibited, restricted or under Community scrutiny. Member states can impose a notification requirement for food fortification. For example in Finland, production or marketing of a fortified food must be notified beforehand to the Food Safety Agency.

Minimum amounts of vitamins and minerals in fortified foods are linked to the notion of significant amount. The Regulation provides for the setting of maximum amounts of vitamins and minerals in fortified foods. The Commission's discussion paper on the setting of maximum and

⁶⁹⁴ Kwak – Jukes 2000b, 112-113.

⁶⁹⁵ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

⁶⁹⁶ “Annex I of the Regulation is a list of vitamins and minerals which may be added to foods. Annex II is a list of the sources of vitamins and minerals which may be added to foods. Annex III is a list of substances whose use in foods is prohibited, restricted or under Community scrutiny. At the end of a transitional period, only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods.” http://ec.europa.eu/food/food/labellingnutrition/vitamins/index_en.htm. EFSA evaluates substances before changing the lists.

⁶⁹⁷ There is a transitional period that lasts until January 2014. During this time, Member States may provide derogations for vitamins and minerals and their forms not included in the Directive. This applies to products that were on the European market in 2007 and on which there is no unfavourable EFSA opinion.

⁶⁹⁸ European Commission. Health and Consumer Protection Directorate General. Administrative Guidance on Submissions for Safety Evaluation of Substances Added for Specific Nutritional Purposes in the Manufacture of Foods. Available at: http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safety_substances_en.pdf.

minimum amounts for vitamins and minerals in foodstuffs is related both to food supplements and fortified foods, and was discussed above. This legislation is expected soon.

Article 8 of the Regulation 1925/2006/EC also gives the possibility to legislate on substances other than vitamins and minerals⁶⁹⁹. This means that fibre fortification might in the future be regulated in the same manner as vitamin and mineral fortification is. Currently, addition of these other substances is regulated only at member state level. The situation is thus the same as with food supplements.

Foods can be fortified for the whole population as well as a specific population group. Some of fortified foods can be sold as *dietetic foods*. For example fortified breakfast cereals cannot be considered as a dietetic food, since dietetic foods are for certain categories of people. If a certain food is distinctively fortified with essential nutrients for the special dietary requirement of a specific group of the population, it could be sold as a dietetic food. A fortified food might even be sold as a medical food (a subcategory of dietetic foods, see above) if its benefits are specified for patients with conditions where medical supervision is necessary.⁷⁰⁰

4.2.1.7 Safety of Novel Foods

Finally, we will discuss the safety of novel foods. For a functional food developer, this might be the most important European legal category to be aware of.

4.2.1.7.1 Background

Throughout history, foods prepared and used in traditional ways have been judged to be safe on the basis of long-term experience. In today's risk analysis, a food is considered safe when we are reasonably certain that it will cause no harm if it is used as intended, under the anticipated conditions of consumption. Some foods are not safe in absolute terms but contain natural toxicants like solanin in potatoes.⁷⁰¹ In these cases, safety is related to how the food is used. In the potato case, we simply do not eat the green part and consider the product safe.

Foods are usually complex mixtures of macro- and micro-constituents. Foods provide energy and nutrients and have traditionally been regarded as natural, beneficial and necessary products whose safety and nutritional value need not be questioned. Regulatory approaches have focused on restricting hazards outside the food itself. This means regulating food additives, processing aids, and contaminants of natural or industrial origin. Foods as such have traditionally not been systematically subjected to nutritional or toxicological evaluation. Nutritional evaluation of foods and of diets has not been performed, but such nutritional evaluations have not been used as a basis for a safety assessment of individual foods.⁷⁰²

⁶⁹⁹ "The procedure provided for in this Article shall be followed where a substance *other than vitamins or minerals*, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers."

⁷⁰⁰ Kwak – Jukes 2000b, 113.

⁷⁰¹ European Food Information Council EUFIC Review 04/2000.

⁷⁰² European Commission Recommendation on Novel Foods, Annex, Part I, Chapter 3.2.

During the 1970s, food technology developed rapidly. New products and processes were developed, especially in response to a perceived shortage of food, particularly a shortage of animal protein. Methods were developed to produce protein foods from new plant and microbial sources, and to use textured plant proteins as meat analogues and extenders. Many countries had experience in evaluating the safety of food additives and contaminants, but there was little experience in evaluating safety of new foods or food ingredients. It was recognised that it was inconsistent to require extensive testing for food additives but not for foods or food ingredients that might be consumed at much higher levels.⁷⁰³

In 1972, the Protein Advisory Group of the United Nations (PAG/UNU) issued Guidelines for the Preclinical Testing of Novel Sources of Protein and Guidelines for the Human Testing of Supplementary Food Mixtures. This was an attempt to ensure systematic safety evaluation of novel foods that had appeared on the market, and focused on novel microbial proteins. The Guidelines were revised and re-issued by the United Nations University in 1983. The scope of the revised Guidelines was expanded to cover Preclinical Testing of Novel Sources of Food and Human Testing of Novel Foods. Novel foods were defined as *foods not previously eaten by humans*. The guidelines identified the main categories of information needed to evaluate the safety of novel foods. They also discussed some of the problems with testing novel food safety.⁷⁰⁴

Testing novel food safety is difficult because they are often complex mixtures of many substances, and because they are used in significant levels and to replace other foods. The usual way to test the safety of a substance in food is to feed it to laboratory animals. There is ample experience of doing this with additives or contaminants. Feeding studies will show the level in the diet at which animals show no adverse effects. After this, the maximum level of intake from human food is estimated to ensure that there is a large safety margin, often more than 100 times. This is possible because the additive or contaminant can be included in animal diets at much higher levels than the anticipated level in human food.⁷⁰⁵

A novel food, on the other hand, is often used at significant levels and might reach a level of 10 percent of a human diet. It is then impossible to feed the food to animals at 100 times higher levels. Even if it was possible to feed the food to animals at higher levels than intended for humans, and the animals would actually eat the food, the food would upset the nutritional balance of the diet. This means the diet of the animal would be worse simply because the test food replaces everything else. As foods are often complex mixtures of macro- and micro-nutrients, it is difficult to determine which nutrients cause the effects in animal studies. This is why new approaches to safety assessment have been developed for novel foods. For example, a novel food is always compared to a conventional counterpart, if applicable.⁷⁰⁶

The UK Government introduced a notification scheme for novel foods including testing guidelines in 1984 and the Netherlands followed. Starting at the beginning of the 1990s, novel food regulation followed scientific development and focused on genetically modified food. International organisations and governments developed guidelines on assessing GM food.

⁷⁰³ European Food Information Council EUFIC Review 04/2000.

⁷⁰⁴ European Food Information Council EUFIC Review 04/2000.

⁷⁰⁵ European Food Information Council EUFIC Review 04/2000.

⁷⁰⁶ European Food Information Council EUFIC Review 04/2000.

After many years of discussion the European Union Novel Food Regulation came into force in 1997.⁷⁰⁷ The Chinese Novel Food Regulation had already come into force in 1990. In Europe, the Regulation has been applied to all foods developed or imported after July 1997. GM foods were separated from the novel food regulation in 2002. Several problems still exist with the regulation of novel foods, and a new European regulation was proposed in 2008.

4.2.1.7.2 European Definition of Novel Food

According to the current EU regulation⁷⁰⁸, novel foods are foods that are new in the context of normal foods: “This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which *have not hitherto been used for human consumption to a significant degree within the Community...*”⁷⁰⁹. The food (or food ingredient) must also fall under the following categories:

- It has *a new or intentionally modified primary molecular structure*.
- It consists of *micro-organisms, fungi or algae*, or is isolated from them.
- It is a food or a food ingredient consisting of/isolated from *plants* or a food ingredient isolated from *animals*, excluded foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use.
- To it has been applied *a novel production process*, where the new process gives rise to *significant changes in the composition or structure* of it, and the changes affect its nutritional value, metabolism or level of undesirable substances.⁷¹⁰

This means that novel foods are foods containing components or ingredients that are not considered natural in relation to the food concerned. Two basic groups of novel foods are foods containing *new synthetic ingredients* and foods containing *new biological ingredients*.

Verhagen et al. (2009) have identified a ‘grey area’ of unidentified novel foods. This means there are new foods on the European market that for some reason are not considered as novel foods. They further divide the grey area of novel foods into two categories:

- (1) food products or ingredients for which the Regulation leaves too much space for interpretations, and
- (2) food products or ingredients that are not novel according to the Regulation, because it contains gaps.

There are several products on the market that fit into these categories. Camel milk, pitaya fruit, acai berry, argan oil, and mangosteen fruit are examples of products where the criterion ‘human consumption to a significant degree’ may be an issue. The cryogenisation process for

⁷⁰⁷ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

⁷⁰⁸ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

⁷⁰⁹ Art. 1(2).

⁷¹⁰ Art. 1(2).

cocoa butter and the processes for making meat substitutes could be examples of ‘significant changes in production processes’.⁷¹¹ Examples of gaps in legislation relate for example to new target groups, growth stages of crops, and single product intake vs. total ingredient intake.⁷¹²

The EU novel food regulation is under reconstruction. The Commission gave its proposal⁷¹³ in January 2008, six years after the Discussion Paper on Novel Foods in 2002⁷¹⁴. A revision of the regulation is deemed necessary in order to “reflect the fact that genetically modified food no longer falls under its scope, to create a more favourable legislative environment for *innovation* in the food industry, and to better *facilitate* both *internal and external trade* in foodstuffs”⁷¹⁵. The European Novel Food Regulation will most likely be totally rewritten with effects also on the definition of novel food. The Commission has proposed the following definition of novel food (Article 2(a) of the proposed Regulation):

- (i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;

The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior to that date, it can be placed on the Community market after that date for the same use without being considered as a novel food. ...

- (ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 1997; and
- (iii) food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances.

⁷¹¹ Verhangen et al. 2009, 4.

⁷¹² Verhagen et al. 2009, 5-6.

⁷¹³ Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure]. COM(2007) 872 final. Brussels, 14.1.2008. The Regulation that will be amended is the Regulation on additives, flavourings, and enzymes, 1331/2008/EC.

⁷¹⁴ Commission gave its discussion paper in 2002: “Discussion paper on implementation of Regulation (EC) No. 258/97 SANCO D4 July 2002”. The discussion paper presented some of the issues that have emerged in relation to the regulation and it also gave future options regarding the possible revision of the regulation. About 40 stakeholders, including e.g. governments, industry, and scholars, gave their comments on the discussion paper. There was also a stakeholder meeting in January 2003. After this, a consult firm prepared a summary of stakeholder views in July 2003 in form of “Summary Report Stakeholder Submissions - Revision of the Novel Food Regulation”. They also gave their recommendations on how to develop the regulation. The next step was that the Evaluation Section of the Commission prepared the “Evaluation Report on the Novel Food Regulation 258/97 Concerning Novel Foods and Novel Food Ingredients”. They also gave their recommendations on how to change the regulation. This was in January 2004. The “summary report” and the “evaluation report” were then summarized in “Evaluation of Regulation (EC) no 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (Novel Food Regulation). Executive Summary.” In June 2006, an online consultation on the revision of Novel Food Regulation (EC) N° 258/97 was launched by the Commission. Based on this, the Commission carried out an impact assessment for a future legislative proposal. Based on the discussion paper, the stakeholder comments, the summary report, the evaluation report, the executive summary, the online consultation, and the impact assessments, novel food regulation is to be revised.

⁷¹⁵ European Commission web page. http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm.

A novel food is not necessarily a so-called functional food, because ‘functionality’ is related to health. Likewise, a functional food is not necessarily novel, because the health effect might be based on ingredients that have been on the market for a long time. Therefore the two types of product are not related in terms of definition and legislative aspects.⁷¹⁶ However, novel food legislation is the safety regulation that a functional food developer will most likely have to deal with. This is if the product in question is a normal food with some health-enhancing novel ingredient(s).

Besides foods in food form, the novel food regulation has been interpreted to apply to *food supplements* as well, i.e. foods in pill form. These foods will have to go through the food supplement procedure *and* the novel food procedure. For example, novel food applications have been made using noni fruit powder, noni leaf powder, or tree lignan in food supplements⁷¹⁷.

There has been some confusion on the issue of whether novel food legislation applies also to *food additives or flavourings*. There is a problem particularly with food ingredients that have multiple purposes, e.g. technological, nutritional and physiological uses. This kind of substance could be used as an additive, as a supplement or as an ingredient in other foods.⁷¹⁸ If there are only technological uses for the novel substance, then authorisation under additive law only would be appropriate. Otherwise, it could be reasonable to authorise all uses in one procedure. The Commission has stated that under the current rules an additive might need an authorisation according to Novel Food Regulation if the safety level laid down for a type of additive does not correspond to the safety level laid down for novel foods.⁷¹⁹

The Commission novel food proposal clarifies the scope of the Regulation. *According to Article 2(2) of the proposed Regulation, it does not apply to additives, flavourings, enzymes, extraction solvents, vitamins or minerals, or GMO foods.*

Applicability of novel food regulation to novel *production procedures* has also been unclear. It is generally understood that this category does not apply to production processes themselves but to foods significantly changed by a new production process. It is generally *not* very well understood, what the “significant changes” are in food composition or structure that bring the process under novel food regulation. According to the Regulation, the resulting product of a novel process is only considered to be a novel food, if the process results in changes in the chemical composition or structure of the food or food ingredient, which affect its nutritional value, metabolism or level of undesirable substances.

According to the Commission Recommendation, this class of novel foods comprises foods and food ingredients which have been subjected to a process not currently used in food production. Examples of novel processes for food production are new types of heat processing, non-thermal preservation methods, new processes to chill or freeze products, to dehydrate products, and the application of new processes catalysed by enzymes⁷²⁰.

In its discussion paper, the Commission suggested three possible options to deal with novel food production processes:

⁷¹⁶ Mogensen 1998, 107.

⁷¹⁷ Finnish Food Agency guidelines on food supplements, updated 2006, pages 22-23.

⁷¹⁸ Executive Summary on Novel Foods 2004, 2.

⁷¹⁹ Executive Summary, 2.

⁷²⁰ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 4.

- a) Remove the category. General food safety regulations are enough to deal with safety of products produced by new techniques.
- b) Category remains. The concept of ‘significant change’ is clarified. This means drafting guidelines and giving expert advice to applicants.
- c) Both novel foods and novel processes are assessed according to Novel Food Regulation.

Option c) was deemed unnecessary as there would not be clear public health or other benefits in subjecting all new processes to a heavy pre-market procedure. This requirement would probably have discouraged development of new processes.⁷²¹ Most stakeholders supported the b) approach where the category of novel procedures remains in the Regulation. Practically everyone stated that the concept of “significant change” should be clarified. The problem with the approach is that the uncertainty can only be reduced, not eliminated altogether.⁷²² There will always be borderline cases.

The Commission has proposed to maintain the category for novel production processes. In preamble 6) of the proposal, it is stated that “novel food should ... include ... foods modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food. The Commission has not defined ‘significant change’ more accurately. Apparently, the Commission has decided to leave this task to EFSA or Committee guidelines.

An important problem in the current definition of novel food is that a food is novel in the EU regardless of its use in third countries. This is a problem mainly to producers of *plant-based products*. For example, Chinese or Andean vegetables or berries that have not been used in Europe are novel foods requiring authorisation, even in cases where they have been used by people for millennia and are considered safe. This approach is similar to the strict European approach towards traditional herbal medicines, discussed below.

Third-country representatives considered the novel food regulation a non-tariff *barrier for trade*. According to Hermann⁷²³, current practice of the regulation has discouraged investment in supply chains, and hindered market development. There might be markets in Europe for example for many different kinds of exotic vegetables, fruit and berries. European consumers might be willing to pay for these “new” products and *more variable diets*. Some of these might be so called functional foods; others might be interesting just for taste. In the other end of the supply chain, production and export of these plant-based products would generate *income for poor farmers* in developing countries. In addition, this would be good for *biodiversity* conservation. Both the third country producers and European consumers would thus benefit from removal of hindrances on South-North trade.⁷²⁴

It is notable that the novel food regulation seems to work in the opposite direction as our very own European public organisations and projects seek to assist developing countries in poverty alleviation. There are, for example, Swiss and Netherlands organisations and numerous research projects that are concerned with linking poor farmers with the market for exotic foods. Besides getting people out of poverty, these efforts aim at adding investment in

⁷²¹ Novel food discussion paper 2002, 15.

⁷²² Novel food discussion paper 2002, 15.

⁷²³ Hermann 2004, 1.

⁷²⁴ Hermann 2004, 1.

biological resources, which have significant underutilised potential in many Southern countries. Questions of ethical trade are closely related: the actors are trying to build economically, socially and environmentally sustainable development. These organisations or farmers do not understand why it is so difficult to get the products into the EU market. In this way there is also a humanitarian aspect to novel food legislation.

In 2006, the EU novel food regulation was discussed as a trade concern at the WTO⁷²⁵. Concerns were raised by Peru, Ecuador, Colombia, Paraguay, the Philippines, India, Bolivia and Brazil.⁷²⁶ These are all countries where different plant-based products compared to Europe are used, putting these plants under the definition of ‘novel food’ in the EU.

In the WTO meetings, Southern countries questioned the justification for giving different treatment to “products of bio-diversity” traditionally consumed outside the EU, compared to foods consumed within the EU.⁷²⁷ This different treatment is of course due to the very definition of novel food: novel foods are essentially foods that have not been consumed in the EU area. There is no tangible scientific ground for this kind of definition. The definition could just as well divide countries into two lists: countries where use counts, and countries where use does not count and scientific evidence on safety is required. Instead of science, the definition is in fact based on practical reasons. It is easier to gather information on familiar substances that are close to the Europeans. It would be too much work to be aware of all the foods used in the world.

The quarrel on the definition of novel food is, not surprisingly, about money. At the WTO meetings, Peru pointed to the cost involved in providing the scientific studies to back up claims of safety. The EU defended the regulation by saying that there are genuine safety concerns for products within the loose category of “products of biodiversity”.⁷²⁸ This is of course true as plants may very well contain poisonous materials. But this reasoning does not justify how some plant products can be considered safe just based on use (use in EU), and some other plant products cannot be considered safe just based on use (use outside EU).

The EU also replied that the scope of application is not limited to third countries, but affects all producers operating in the EU market. This is true, as the regulation applies to all foods marketed in the EU after 1997. Also European producers using Southern plants as raw material must go through the novel food procedure if they would like to sell their product in Europe. The Southern countries have never claimed the regulation is discriminatory in relation to those who use the Southern plants. They merely cited the fact that Southern plants are considered novel, European plants not.

As a sign of perhaps being willing to change the definition of novel food, the EU said it welcomed examples of products approved in other markets and for which the regulation creates obstacles for development. They said this kind of information is useful in the further elaboration of the regulation.⁷²⁹ The Commission has received this same message in gathering stakeholder opinions. The current situation in practice is that many exotic foods are sold without novel food authorisation. The marketers do not consider their foods novel or take the

⁷²⁵ The March meeting and the June meeting of the SPS Committee (the WTO committee dealing with plant and animal health and food safety - sanitary and phytosanitary measures).

⁷²⁶ WTO web page. http://www.wto.org/english/news_e/news06_e/sps_june06_e.htm.

⁷²⁷ WTO web page. http://www.wto.org/english/news_e/news06_e/sps_june06_e.htm.

⁷²⁸ WTO web page. http://www.wto.org/english/news_e/news06_e/sps_june06_e.htm.

⁷²⁹ WTO web page. http://www.wto.org/english/news_e/news06_e/sps_june06_e.htm.

deliberate risk of getting caught and being removed from the market. The novel food process is considered too burdensome and unpredictable. When a law is impossible to live by, it is not obeyed.

According to the Proposal, plants not used in Europe are still considered novel but a simplified procedure is created for them. “Traditional food from a third country” is defined as “novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least one generation in a large part of the population of the country”⁷³⁰. We will return to the principal and simplified procedures in the next chapter.

Currently, the marketer must himself determine whether his product is novel according to the Regulation. This means the *burden of proof* is on the marketer on whether for example his product has been sold before 1997 or whether there is substantial equivalence to another product. If the producer is unsure of whether the product is novel, he can consult the authorities. The process of determining whether a food or food ingredient falls within the scope of the definition is in Article 13 of the Novel Foods Regulation⁷³¹. According to Article 13, the Commission Standing Committee for Foodstuffs can be consulted by the applicant or by the national authority of the member state.

Several stakeholders have indicated that they would appreciate an instrument whereby they could obtain a decision on whether or not their products are novel foods. This kind of advanced decision could be made by EFSA. The ruling would have legal validity throughout the EU. This would remove some of the costs related to uncertainty and thus promote innovation in foods⁷³². It has also been suggested that a publicly accessible novel food database be created. In this database or network, information on novel food status of individual products could be exchanged.⁷³³

According to the Proposal⁷³⁴, where necessary, it may be determined in accordance with the procedure referred to in Article 14(2), whether a type of food falls within the scope of the Novel Food Regulation. The procedure in Article 14(2) means the Committee procedure. The Commission’s Standing Committee on Food Chain and Animal Health will resolve the issue of whether the food is novel. According to the definition of novel food⁷³⁵, the Committee will also set further criteria for assessing if a food has been used for human consumption to a significant degree within the Community before 15 May 1997. This will probably be done in the form of scientific opinion or guideline.

⁷³⁰ Article 3(2)(b) of the proposed Regulation.

⁷³¹ Art. 1(3).

⁷³² According to CIAA, uncertainty of novel food procedures is detrimental to innovation and new product development. The first uncertain issue here is whether a food is novel in the first place. CIAA: Economic impact assessment of the way in which the EU novel foods regulatory approval procedures affect the EU food sector.

⁷³³ Novel food summary report 2003, 4.

⁷³⁴ Article 2(3) of the proposed Regulation.

⁷³⁵ Article 3(2)(a)(i) of the proposed Regulation.

4.2.1.7.3 Current Procedures of Evaluating Safety

Currently, there are two different novel food procedures in use. Pre-market authorisation is the primary procedure. Pre-market notification (the simplified procedure) applies to foods that are *substantially equivalent* to existing foods.

WHO and OECD originally introduced the concept of substantial equivalence with particular reference to GMO foods. The concept of substantial equivalence embodies the idea that existing organisms used as foods can serve as a basis for comparison when assessing the safety of a modified or new food. If a new food is found to be substantially equivalent to an existing food, it can be treated in the same manner with respect to safety.⁷³⁶

The application of the principle of substantial equivalence was extended from the evaluation of GMO foods to the evaluation of foods from novel sources and processes. In terms of safety, substantially equivalent novel foods are comparable to their conventional counterpart. *Establishment of substantial equivalence is not a safety or nutritional assessment in itself*. Conversely, if a novel food is not substantially equivalent to an existing food or food component, this does not imply that it is unsafe. It merely indicates that such a food must be evaluated on the basis of its unique composition and properties.

The establishment of substantial equivalence is thus “an approach to compare a potential new food with its conventional counterpart”. The notion implies that the *substantially similar novel foods are presumed just as safe as traditional foods*. From a risk management perspective, this leaves a lot of questions unanswered. *We don't know exactly how safe traditional foods are*. We just don't know all the diet-health mechanisms. A food might be similar to a traditional food that will later prove dangerous. A food might be almost identical to a safe food, but the slight difference might make it dangerous.

According to the Commission, the establishment of substantial equivalence contains a dynamic element. This means that when a food is continually modified, the basis of comparison changes. The most recent novel food is compared with an appropriate former novel food and not necessarily with the most traditional counterpart.⁷³⁷ A consumer is reassured by the presumption that “another little change will probably be meaningless”.

The comparison of the old food and the novel food may be simple or very lengthy depending upon experience with and the nature of the novel food in question. The technical approach to establishing substantial equivalence differs between whole animals, plants, microorganisms, chemical food ingredients and novel processes.⁷³⁸

The advantages of the comparative approach are:

- the comparator defines a standard that meets the acceptable level of safety,
- it is practicable, and
- animal tests are restricted to situations where they are of real value.⁷³⁹

Again we see that food law is not based on pure science but practical issues. We cannot analyse all the foods on the market, so we presume the old foods are safe. We also presume

⁷³⁶ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.3.

⁷³⁷ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.3.

⁷³⁸ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.3.

⁷³⁹ European Food Information Council EUFIC Review 04/2000.

that novel foods are safe if they are equivalent to old foods. Besides being unscientific and discriminatory, the concept of substantial equivalence is unavoidably blurred.

The decision on the authorisation of a novel food is made jointly for the whole EU and Member States, and Commission takes part in this decision-making. At present, novel food applications are lodged with Member States. They make the Initial Assessment of the safety of the product. In practice, the process has always continued from initial assessment to a Community decision⁷⁴⁰. For example in Finland, the Food Agency handles applications on novel foods. There is an expert body called the Board of Novel Foods that assesses the applications from the safety point of view.

An alternative for the current system is that applications are to be lodged with the EFSA. This would be simpler, in that applicants would still deal with a single authority. Applicants would not have to go through the occasional artificial process of selecting which Member State is the one where they first market a food. Also consistency of decisions might improve. This would promote legal certainty and equality of applicants. During the Commission's consultations, the majority of stakeholders were of the view that the EFSA should handle novel food applications, as it is an impartial scientific organisation consisting of food science experts.

In its Discussion paper, the Commission identified the major problem of the novel food process as being too lengthy. It has been a constant complaint that the current two to three years is too long of a period for the assessment to last. The novel food process significantly postpones the time of the product accessing the market. With medicines, there are absolute timeframes in which the authorities must handle the application. The food industry is reasonable in demanding similar treatment. Setting exact timeframes would make the legal treatment more predictable and facilitate planning by entrepreneurs.

In their comments to the Commission discussion paper, stakeholders were unanimous in urging the Commission to streamline the decision-making procedure in order to make it quicker. However, the quality of risk assessment and risk management cannot be compromised. One important suggestion by the stakeholders was that there should be *strict deadlines* for each stage of the procedure. These deadlines would apply to the EFSA and the Commission.⁷⁴¹

Many stakeholders believed that putting the EFSA in charge of the risk assessment would speed up things, particularly if applications will in the future be filed directly with the EFSA. Stakeholders also trust the EFSA to make quality assessments, see above. All stakeholders agree that legal recourse against a decision to authorise or not authorise a novel food should be guaranteed. This would also be according to European on Human Rights, where every person is guaranteed to appeal a decision affecting his or her rights or responsibilities.

The novel food process has been strongly criticised by the European food industry for being unpredictable and anti-innovation. According to the CIAA, most in the food industry have always known that "food innovation in Europe is not possible without a fundamental reform of current procedures"⁷⁴². According to a report prepared for the CIAA in 2007, R&D expenditure on food products by companies tends to be lower in the EU compared to other countries. Also, the EU tends not to be the highest priority target market for new food product development. As a result, improved products are not available to European consumers. The

⁷⁴⁰ Novel Food Discussion paper 2002, 21.

⁷⁴¹ Summary Report 2003, 2.

⁷⁴² CIAA Statement on proposed Novel Food Regulation. 14.1.2008.

report also suspects that income and employment generation in the EU are lower than they would be in a “more innovation-friendly regulatory environment”.⁷⁴³

The CIAA report identifies major impacts of the current EU Novel Foods Regulation that contribute to explaining why food companies tend to ignore the EU market for novel product development, as compared to the US market. First, there is the uncertainty regarding the novel food status and the timing of the procedure. There is a risk of delays of three years to five years in obtaining approval. This uncertainty has made some investments of marginal value, and significantly diminished the economic incentive to bring products to the EU market. Secondly, the current approval mechanism encourages companies to be market followers rather than innovators. Followers to market experience lower costs and risks than novel food innovators, and hence can easily earn higher rates of return than innovators.⁷⁴⁴

The report concludes that if the EU Novel Foods regulation is to better create an environment that encourages food innovation, each of these deficiencies should be addressed. The time taken to authorise a novel food should be reduced. Incentives to encourage innovation should be considered. For this purpose, the report suggests exclusive access to markets or compensation for data provision. Uncertainties should be minimised.⁷⁴⁵

4.2.1.7.4 Proposed Procedures

Common Procedure

According to the Commission proposal, novel foods will in the future be evaluated by the EFSA in the Common Procedure for novel foods, additives, flavourings, and enzymes⁷⁴⁶. According to preamble 17 of the proposed Novel Food Regulation, “in order to simplify procedures, applicants should be allowed to present a single application for foods regulated under different sectoral food laws”. This means that a substance that has multiple uses can be authorised in one procedure, for example as a novel food and as an additive.

As regards the procedure for updating the Community list, the proposal for Novel Food Regulation, more particularly its Article 7, refers to the proposal on the Common Procedure, more particularly its Article 14, which in turn refers to the Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission. It would be clearer for the marketers if the novel food evaluation procedures were described in the Novel Food Regulation itself.

The Common Procedure is based on risk assessment carried out by the EFSA and a risk management system in which the Commission and the Member States operate within the framework of a regulatory committee procedure. This means the Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health. On the basis of scientific assessments by EFSA, the Commission creates, maintains, and updates a general positive list for each category of substances concerned. The lists and their updates will be given in

⁷⁴³ Brookes 2007, 6.

⁷⁴⁴ Brookes 2007, 6.

⁷⁴⁵ Brookes 2007, 6.

⁷⁴⁶ Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

the form of regulations. The inclusion of a substance on one of the lists means that its use is authorised in general for all operators on the Community market.⁷⁴⁷ The Commission will make decisions on the lists based on EFSA opinions, Community law, and “other legitimate factors”⁷⁴⁸.

There are strict timelines involved in the Common Procedure. Applications will be sent to the Commission, which will seek an opinion from the EFSA. The EFSA will have 6 months to give their opinion⁷⁴⁹. After this, the Commission will have 9 months to give their draft Regulation⁷⁵⁰. The Standing Committee on Food Chain and Animal Health shall deliver its opinion within a time limit, which the chairman may lay down according to the urgency of the matter⁷⁵¹. After this, the Commission shall adopt the measures envisaged, if they are in accordance with the opinion of the Committee⁷⁵². If the opinion is not in accordance with the draft regulation, the matter will be submitted to the Council, which will have 3 months to adopt it or oppose it. If the Council does neither, the Commission may adopt the proposed regulation.⁷⁵³

The timelines indicate that the procedure as a whole should generally last not much longer than one and a half years. Timelines are what the industry has wanted of novel food evaluation, and the proposed procedure is an improvement compared to current novel food procedures. Novel food producers should also be satisfied with the EFSA being in charge of risk assessment. The EFSA is trusted by the industry as an impartial actor.

According to Article 6 of the proposed Novel Food Regulation, “a novel food may be included in the Community list only if it meets the following conditions:

- a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer under normal consumption conditions;
- b) it does not mislead the consumer, by the way it is presented or by its intended use;
- c) in the case where it is intended to replace another food, it does not differ from that food to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer”.

According to Article 10 of the proposed Novel Food Regulation, in assessing the safety of novel foods, the EFSA shall:

- (a) compare, where appropriate, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;
- (b) take into account for traditional food from a third country, the history of safe food use.”

⁷⁴⁷ Commission Proposal COM (2006) 423 final, page 2 (Explanatory Memorandum).

⁷⁴⁸ Article 3(4) and Article 7 of the proposed Regulation on the Common Procedure.

⁷⁴⁹ In duly justified cases where the EFSA requests additional information from applicants, the period may be extended. Article 6(1) of the proposed Regulation on the Common Procedure.

⁷⁵⁰ Article 7 of the proposed Regulation on the Common Procedure. The 9-month period may be extended if the Commission needs additional information from applicants. Article 8(1).

⁷⁵¹ Decision 1999/468/EC, Article 5(2).

⁷⁵² Decision 1999/468/EC, Article 5(3).

⁷⁵³ Article 14(2) of the proposed Regulation, referring to Article 5(6) of Decision 1999/468/EC. The Parliament will also be informed on the proposal, and it may force the Commission to re-examine the measures.

The safety test is a comparison. The novel food is compared to the old EU food, which is presumed safe. Also with third country foods, safety is presumed to be based on long-term use. Safety in absolute terms would be impossible to achieve. However, research will continue to bring negative impacts of old foods to our knowledge. *The concept of presuming familiar things safe is used in law not only for scientific but for practical and political reasons.* Even though used in regulation, this kind of presumption cannot be the base of natural science.

Traditional Foods from Third Countries

By the current Regulation, the novelty of plants, animals or microorganisms is defined by their novelty in the Community. Species not previously used in Europe are considered new, and a full description is needed to assess their role in the European food supply. With reference to history of the organism, the description should include information on the past and present use of the food in other parts of the world. Such information should also include past and present methods to obtain raw materials and food, e.g. by raising, harvesting, slaughtering, and capture, procedures for fermentation and preparation, description of transport and storage conditions, and its traditional role in the diet at locations outside the Community.⁷⁵⁴

Considering information on previous human exposure to the novel food, it is acknowledged that documentation on previous use of the novel food source in the Community or in other parts of the world is important to establish a baseline for assessment. However, it is also firmly stated that *history of food use outside the Community is not of itself a guarantee that the novel food can be safely consumed in the Community.* There might be traditional handling and preparation habits that prevent adverse effects of foods that in other conditions might be toxic. These cultural issues must be included in describing human exposure to the food.⁷⁵⁵

In its discussion paper, the Commission presented different alternatives for the new simplified procedure:

- a) Simplified procedure for exotic traditional foods (with history of safe use in third countries).
- b) *Three different categories of novel foods with different requirements and procedures:*
 - innovative products with claimed consumer benefits,
 - innovative products without claimed consumer benefits, and
 - exotic traditional foods.
- c) *Only one procedure* and same safety requirements for all products.

As stated above, the Commission eventually chose option a). Option c) seems fair and would have been the clearest one. In practice, it would have been unreasonably burdensome to demand all the same scientific evidence of all novel foods. Option b) would have been analogous to pre-market approval of medicines: Every product would go through pre-market approval process, but products are subject to different requirements as to the type and quantity of data they must provide.⁷⁵⁶ By option b), the Commission must have meant that health claim

⁷⁵⁴ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 5.

⁷⁵⁵ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 5.

⁷⁵⁶ Novel food discussion paper 2002, 20.

evaluation would, if necessary, be added on top of the novel food procedure. Safety evaluation as such would have been the same for innovative products with and without claims.

After the long debate and problems at the WTO, the proposed Regulation creates a new procedure for traditional foods from third countries (Article 8). They are still considered a subcategory of novel foods, but they are not included in the Community list of authorised novel foods. Instead, a separate list of traditional foods will be created and published on the Commission website.

According to the Proposal, a food business operator intending to place a traditional food from a third country on the market in the Community shall notify it to the Commission. The notification must indicate the name of the food, its composition and country of origin. The notification shall be accompanied by documented *data demonstrating the history of safe food use in the third country*.⁷⁵⁷ According to proposed Article 3(2)(c), “history of safe food use” means that the safety of the food in question is confirmed with compositional data *and* from experience of use *and* continued use in the normal diet of a large part of the population of a country. This means the marketer will still be required to show safety, and it may be a complex task.

The Commission shall forward the notification including the demonstration of history of safe food use without delay to the Member States and the EFSA⁷⁵⁸. Within four months from the date on which the notification is forwarded by the Commission, a Member State and the EFSA may inform the Commission that they have reasonable safety objections, based on scientific evidence, to the placing on the market of the traditional food concerned. In that case, the food shall not yet be placed on the market, and the notification will transform into an application in the primary procedure for authorisation of novel foods. The Commission will inform the food business operator of objections within five months of the notification.⁷⁵⁹

If no reasoned safety objections, based on scientific evidence, have been raised and no such information has been communicated to the food business operator itself, *the traditional food may be placed on the market in the Community after five months from the date of the notification*. The Commission shall publish a list of traditional foods from third countries that may be placed on the market in the Community⁷⁶⁰.

The proposed procedure seems reasonable from the viewpoint of the marketer: in five months, he will either have a permission to put the product on the market, or he will have learned about his notification being objected and transferred into an application. It remains to be seen whether the Member States will try to reject traditional food notifications on artificial grounds. In that case, the notification procedure would lose its benefits, waste time, and only create an additional hurdle to reaching the market.

4.2.1.7.5 Required Scientific Evidence on Safety

Even though the procedures change, the Commission Proposal does not intend to alter the scientific evidence required to show safety, apart from creating the new simplified procedure for traditional foods. The detailed requirements for novel food applications are specified in the Commission

⁷⁵⁷ Article 8(1) of the proposed Regulation.

⁷⁵⁸ Article 8(2) of the proposed Regulation.

⁷⁵⁹ Article 8(3) of the proposed Regulation.

⁷⁶⁰ Article 8(5) of the proposed Regulation.

Recommendation 97/618/EC⁷⁶¹. Scientific aspects of the information necessary to support applications are specified in the Annex of the Recommendation, Part I. The information should be presented according to Part II of the Annex. Member States should draw up their initial assessment reports according to Part III of the Annex.

When new ingredients are used or a food is produced in a new way, the implications for *consumer safety and nutritional value* require consideration. Information is needed on any issue relating to both these aspects.⁷⁶² This information must be included in a novel food application⁷⁶³.

Safety evaluation includes toxicity tests, showing the product does not cause mutations and cancer. The assessment of the nutritional value of foods presents further scientific challenges. Foods are complex chemical mixtures, which are more difficult to evaluate than the impact of a single chemical. We don't know the exact mechanisms on how different patterns of nutrient intake affect health. For example, so-called modifiers of toxic effects might be naturally present in certain foods. It is thus difficult to exactly define the concept of nutritional balance.⁷⁶⁴

Analytical studies of the composition of the novel food are required. Studies are needed for the establishment of substantial equivalence, in which case the simplified procedure applies, and as a prerequisite for nutritional and toxicological assessments. Study methods have to be standardised and validated, and the analyses and data presented have to be based upon sound scientific principles. Both substances inherently present and substances derived from the process must be analysed. Investigations should focus especially on determining contents of:

- *critical nutrients* (both macro- and micronutrients), and
- *critical toxicants and anti-nutritional factors*.⁷⁶⁵

Toxicological requirements for a novel food are considered on a case-by-case basis. Toxicological data is needed in three different scenarios:

- 1) Substantial equivalence can be established to an accepted traditional food or food ingredient. In this case, no further testing is needed.
- 2) Substantial equivalence can be established except for a single or few specific traits of the novel food. In this case, further assessment of safety should focus specifically on these traits.
- 3) Neither partial nor total substantial equivalence can be established. In this case, the wholesomeness of the whole novel food or macronutrient has to be assessed using an appropriate combined nutritional-toxicological approach.⁷⁶⁶

⁷⁶¹ 97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council.

⁷⁶² Commission Recommendation, Annex, Part I, Chapter I.

⁷⁶³ Hermann 2004, 7. Wheat has considerable allergenic potential due to the presence of gluten proteins, potatoes involve hazards posed by glycoalkaloids (green colour caused by sunshine), and green leafy vegetables contain nitrate and oxalate.

⁷⁶⁴ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.2.

⁷⁶⁵ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.4.

⁷⁶⁶ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.7.

In scenario 3), the wholesomeness assessment has to take into account:

- identity, chemical structure and physico-chemical properties of the novel food,
- potential intake based on the proposed use,
- potential exposure of particularly vulnerable population groups, and
- the likely effects of processing.⁷⁶⁷

Nutritional implications must be considered both at expected normal intakes and at maximum levels of consumption. Evaluation is based on literature, product compositional analysis and, if needed, data from animal studies. Attention should be paid to particular nutritional needs of groups such as infants, children, pregnant and lactating women, the elderly, and those with chronic diseases like diabetes. The greater the role of the product in the diet the more extensive the nutritional assessment must be. Human nutritional assessment data are needed both on short-term and long-term effects.⁷⁶⁸

Nutritional and toxicological aspects are integrated in the assessment of a novel food. Nutritional properties of the food (e.g. energy value, protein content, and bioavailability of micronutrients) affect the toxicological testing programme: the anticipated role of the product in the diet determines how much food is given to test animals.⁷⁶⁹ The greater the predicted dietary exposure the more extensive the required toxicological testing programme will have to be.⁷⁷⁰

However, it is impossible to predict exactly how much the product will be used and what products it will replace. This is why a *surveillance programme* should accompany marketing of a novel food. The consumption pattern might affect the acceptability of the novel food.⁷⁷¹ This notion is rather unclear because the presumption is that a novel food cannot be authorised if it is unsafe or unwholesome. Because the surveillance programme is a recommendation only, consequences for not following the surveillance programme are unclear.

Foods and food ingredients which fall within the scope of the novel food regulation, can be divided in categories which differ in complexity and in the issues that need to be addressed. These categories are:

- simple chemically defined substances or mixtures of these,
- complex foods such as plants, animals, micro-organisms or food components such as fats, proteins, or fibre; and
- foods processed in a novel procedure.⁷⁷²

The Commission Recommendation gives structured schemes on the types of information that are considered essential to establish the safety of particular classes of novel foods. The Recommendation is not legally binding, and the schemes are therefore provided “for guidance only”. However, if an applicant wants to omit certain information from a dossier requested in any of the schemes, the scientific justification for this should be given. The results of any other

⁷⁶⁷ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.7.

⁷⁶⁸ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.8.

⁷⁶⁹ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.6.

⁷⁷⁰ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.7.

⁷⁷¹ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 3.5.

⁷⁷² Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 4. In the Recommendation, there are additional three categories listed for GM products, which no longer fall under the novel food regulation.

investigations (not required by the schemes) relevant to safety assessments, which have been carried out must be reported.⁷⁷³ In practice, the information according to the Recommendation is usually the required minimum information.

The information schemes are the following:

- Specification of the novel food,
- Effect of the production process applied to the novel food,
- *History of the organism* used as the source of novel food,
- Anticipated intake and extent of use of the novel food,
- *Information on previous human exposure* to the novel food or its source,
- Nutritional information on the novel food,
- Microbiological information on the novel food,
- Toxicological information on the novel food.⁷⁷⁴

The need for *comparative data* between the novel food and its counterpart are emphasised in these schemes. The *presence of new toxins, anti-nutritional factors or allergens* (or increased levels thereof) will indicate the need to assess their safety implications. The nutritional impact of the novel food introduction into human diets must always be assessed, unless the old food and the novel food are nutritionally equivalent.⁷⁷⁵

4.2.1.7.6 Decisions / Regulations?

The third important question with novel foods, besides what is considered novel and what is considered safe, is whether others can market the novel food after one company has received authorisation. At the moment, decisions under the Novel Food Regulation are addressed to the applicant. If authorisation is granted, only the applicant is able to place the novel food in question on the market. Another marketer must submit another application or notification.

There are in essence two alternatives to manage the issue:

- a) Decisions addressed to individuals.
- b) Regulations with general application.

According to the Commission, decisions have the advantage that they provide the regulator with more certain and comprehensive information about the novel foods that are legally on the market.⁷⁷⁶ When they know the firms that have applied, it is easy to determine that other marketers are conducting illegal business. The decision approach also allows enforceable conditions to be attached to the decision. By this, the Commission means that for example post-market surveillance requirements can easily be imposed on the firm in question.⁷⁷⁷ This is because the Commission knows the names of the firms by the fact that they have applied. It is

⁷⁷³ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 5.

⁷⁷⁴ Commission Novel Food Recommendation 1997, Annex, Part I, Chapter 5.

⁷⁷⁵ European Food Information Council EUFIC Review 04/2000.

⁷⁷⁶ Novel food discussion paper 2002, 17.

⁷⁷⁷ Novel food discussion paper 2002, 17.

more difficult to impose precise obligations to parties that are not known by the Commission, and perhaps do not even themselves know that their product is a novel food and that they have certain legal criteria that bind them.

A possible downside of the decision approach is, according to the Commission, that creating effective monopolies may not be advisable unless there are very good grounds for it.⁷⁷⁸ After all, freedom of competition is one of the cornerstones of the European Union.

The regulation approach, on the other hand, has the benefit of being binding to all relevant parties, indicating the labelling requirements are binding on all the sellers of the product, not just the applicant. The regulation approach would save the authorities from multiple applications, and it would also save the competitors from monopolies.⁷⁷⁹ The regulation could also include other uses for the food products than the ones that the applicant applies for. For example it could include the use of a berry in juice, jam, etc.

The Commission has indeed proposed the regulation approach: it is proposed that *a Community list of authorised novel foods will be created*⁷⁸⁰. The list would be applicable to all, and only novel foods on the list could be placed on the market. At the same time, a system of rewarding applicants with data exclusivity for 5 years has been suggested. This is a compromise between the decision approach and the regulation approach, and corresponds to the Regulation on claims, which also created the Community lists and the 5-year protection for proprietary data. With medicines, proprietary data included in the application is protected for 10 years.

Article 12 of the proposed Regulation stipulates the rules on proprietary data:

“On request by the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and proprietary scientific data provided to support the applications, may not be used for the benefit of another application during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant.”

According to preamble 20 of the proposed Regulation, the data exclusivity is granted “under specific circumstances in order to stimulate research and development within the agri-food industry, and thus innovation”. The protection of scientific data provided by one applicant does not prevent other applicants from seeking the inclusion in the Community list of novel foods on the basis of their own scientific data⁷⁸¹. This means a competitor can choose between:

- producing the same or similar data himself: comparing the toxicological and nutritional properties of an old food and the novel food,
- reaching an agreement with the first applicant to use the data, in practice: buying the data from the first applicant,
- waiting 5 years and using the first applicant’s data free of charge.

The 5-year exclusivity sounds similar to an intellectual property right. However, patent protection is more far-reaching as it blocks competitors even if competitors developed the

⁷⁷⁸ Novel food discussion paper 2002, 18.

⁷⁷⁹ Novel food discussion paper 2002, 17.

⁷⁸⁰ Article 5 of the proposed Regulation.

⁷⁸¹ Preamble 20 of the proposed Regulation.

invention themselves⁷⁸². Patent protection is also longer: 20 years. According to the European patent convention, patent protection is available for a product or a method that is novel, involves an inventive step and is susceptible of industrial application⁷⁸³. Some innovative foods are thus also eligible for patent protection. The patent application could also be done in vain, in case of the novel food application being rejected.

One could argue that patent protection is enough and that other kinds of exclusivity rules are not needed. A company could patent what is patentable, and other innovations would be available to competitors in the spirit of freedom of competition. However, data exclusivity of a novel food application is different from protecting the product itself. The 5-year rule rewards the performing of safety tests on the product, not the product innovation. The patent system is not faultless in promoting innovation, hence other forms of intellectual property, proprietary rights, and data protection are created.⁷⁸⁴

Trademark protection is another issue. It could be argued that trademarks are enough, and that no rules on data exclusivity are needed. The marketer of a novel food can register the name of the product as a trademark. If no period of exclusivity were granted, the developer of the novel food would still be the first to market, have some lead on his rivals, and be in the best position to build his brand to make himself the market leader. However, this lead has not been considered sufficient by food industry operators to make innovation profitable, at least according to the 2007 report produced for the CIAA. Based on data exclusivity, the trademark and brand holder will have more time to recoup his investment and to build his brand among the consumers.

One might think that small companies, which are often market followers, would have preferred the full regulation approach where they can simply copy the large company. However, we cannot only focus on the followers. The compromise version might be best for all companies as it always rewards the first to market. The compromise approach leaves the copying competitor three different options between which he can choose, based on cost-efficiency: to duplicate the effort, to agree with (pay for) the first to market, or to wait for 5 years and follow.

4.2.1.8 *Safety of Genetically Modified Foods*

Genetically modified organisms (GMOs) are organisms in which man has altered the genetic material (DNA). The technology that enables this is called “modern biotechnology”, “gene technology”, “recombinant DNA technology” or “genetic engineering”. It allows selected individual genes to be transferred from one organism into another. Genes are today modified primarily to improve crop protection. This is done by transferring bacterium or virus genes that give the plant greater resistance against insects or viruses, or increased tolerance towards herbicides. Under development are plants with improved disease or drought resistance, crops with increased nutrient levels, fish species with enhanced growth characteristics and plants

⁷⁸² If the competitor used the invention at the time of the patent application, he may be granted a licence. If he used it at the time when the application became public, he may be granted a compulsory licence.

⁷⁸³ Articles 54, 55, and 57 of the European Patent Convention.

⁷⁸⁴ Here we must mention that some European countries have rules on utility model protection. This “little patent” could be suitable for many food products, but is not available everywhere.

or animals producing pharmaceutically important proteins such as vaccines.⁷⁸⁵ Globally, new GMO foods must go through pre-market safety evaluation.⁷⁸⁶

EU legislation on GMO approval has been in place since the beginning of the 1990s. Between 1991 and 1998, the marketing of 18 GMOs was authorised in the EU by a Commission decision. Then began the so-called moratorium, during which no authorisations were granted due to resistance to the whole idea of GMO food. New EU legislation on GMO foods came into force in 2004. This includes the regulation on genetically modified food and feed⁷⁸⁷, its implementing regulation⁷⁸⁸, and the GMO traceability and labelling regulation⁷⁸⁹. Until April 2004, GMOs were evaluated under novel food legislation. The new regulatory framework on GMOs aimed to address the concerns of EU Member States and EU consumers. It was designed to build confidence in the authorisation system so that the moratorium could be ended.⁷⁹⁰

The GMO food regulations apply to:

- (a) GMOs for food use;
- (b) food containing or consisting of GMOs
- (c) food produced from or containing ingredients produced from GMOs⁷⁹¹.

Food produced “from” a GMO is covered; food produced “with” a GMO is not. The determining criterion is whether or not material derived from the genetically modified source material is *present* in the food. Processing aids, which are only used during the production process, are not covered by the definition, because they are not expected to become an ingredient of the food.⁷⁹²

GMO food must not:

- (a) have adverse effects on human health, animal health or the environment;
- (b) mislead the consumer;

⁷⁸⁵ WHO web page. <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

⁷⁸⁶ According to WHO, the safety assessment of GM foods generally investigates: “(a) direct health effects (toxicity); (b) tendencies to provoke allergic reaction (allergenicity); (c) specific components thought to have nutritional or toxic properties; (d) the stability of the inserted gene; (e) nutritional effects associated with genetic modification; and (f) any unintended effects which could result from the gene insertion”. <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

⁷⁸⁷ Regulation 1829/2003/EC of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

⁷⁸⁸ Commission Regulation 641/2004/EC of 6 April 2004 on detailed rules for the implementation of Regulation 1829/2003/EC of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

⁷⁸⁹ Regulation 1830/2003/EC of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

⁷⁹⁰ WHO web page. <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

⁷⁹¹ Regulation 1829/2003/EC, Article 3.

⁷⁹² Cana – Schliessner 2005. Here we only discuss safety rules of final products. Contained use of GMOs is covered by Directive 90/219/EEC, and deliberate release into the environment of GMOs by Directive 2001/18/EC.

(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer⁷⁹³.

There is a single European authorisation procedure that covers both human food and animal feed. Applications are submitted first to the competent authority of the Member State where the product is first to be marketed. The application is then made available to the EFSA, which is responsible for the scientific risk assessment. The Commission will draft a proposal for granting or refusing authorisation. The Standing Committee on the Food Chain and Animal Health will approve the Commission's proposal. If the Committee does not approve the proposal, the draft Decision is submitted to the Council of Ministers, which can either adopt or reject it. If the Council does not act within three months or does not obtain a qualified majority for the adoption or rejection of the Commission's proposal, the Commission shall adopt the decision.⁷⁹⁴

Foods containing maximum 0.9 percent GMOs⁷⁹⁵ are excluded from the scope of the EU GMO food regulations, provided that this presence is adventitious or technically unavoidable. GMOs approved so far have been maize and soy derivatives, rapeseed oil and cottonseed oil⁷⁹⁶. Post market monitoring of GMOs is performed by national food agencies.

European consumers remain unenthusiastic about GMO food due to several factors. When GMO foods first came to the European market, the consumers could not see the benefit of them. The products were not less expensive and did not taste better. The European consumers also distrust risk assessments, as there have been several food safety scandals in Europe particularly in the 1990s⁷⁹⁷. Generally, consumers tend to accept gene technology in medicine much easier than gene technology in food⁷⁹⁸. This is related to the basic ideas of foodstuffs and medicines: medicines are used based on a calculation of risks and benefits to health. Everyone acknowledges that medicines have side effects. For foods, unfamiliar risks related to one's health are not accepted.

The Commission assessment reports of the GMO Regulations 1829/2003/EC and 1830/2003/EC have been published⁷⁹⁹ but no revision of the Regulations is planned. The CIAA wants the European Commission to recognise that GMO contaminations can occur, despite the efforts of all partners in the food chain. They say discussion on the enforceability of the European GMO regulatory system is necessary.⁸⁰⁰ According to the WHO, feasibility and methods for post-marketing monitoring of GMO food products are under discussion⁸⁰¹.

⁷⁹³ Regulation 1829/2003/EC, Article 4.

⁷⁹⁴ European Commission web page. http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf.

⁷⁹⁵ Of the food ingredients considered individually.

⁷⁹⁶ European Commission web page. http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm.

⁷⁹⁷ WHO web page. <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

⁷⁹⁸ WHO web page. <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

⁷⁹⁹ Report from the Commission to the Council and the European Parliament on the implementation of Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. COM(2006) 0197 final.

⁸⁰⁰ Review of CIAA Priorities and Objectives for Better Regulation In light of the Commission proposals to simplify EU legislation. CPT/003/07E-Final Brussels, 28 February 2007 Page 5.

⁸⁰¹ WHO web page. <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

4.2.2. China

4.2.2.1 *The Challenge of Food Safety in China*

Food safety is today a major concern in China. It is important both for Chinese food export and domestic markets⁸⁰². Food safety efforts are more advanced in the export sector⁸⁰³, and more recently in the domestic sector. According to Calvin et al., “China’s efforts are an important case study of a country’s striving to elevate standards in its food and agriculture sector to international food safety standards”⁸⁰⁴.

For exported food, the Chinese government has succeeded in arranging a strict regulation system. It is usual that developing countries have, to promote their exports, stricter standards for exported food. The Chinese system was created as a response to bans of Chinese food in foreign countries. The Export-Oriented System monitors food products from exporting companies at every step, from the pesticides and chemicals used on farms to food processing facilities to packaging plants. Exporting food companies must obtain special licences from the Export-Oriented System administration.⁸⁰⁵ The approach taken resembles the European farm-to-table approach.

The reasons for regulating the export industry stricter are:

- The export industry is easier to regulate because it is smaller than the general food industry.
- The export industry is a more motivating target as the exports generate considerable revenue, and China wants to keep up its international reputation.⁸⁰⁶

According to Calvin et al, many of China’s food safety problems can be traced back to the *farm level*. It is difficult to standardise and monitor production practices of the Chinese food production sector, which is composed of 200 million farm households. Important issues include both chemical and biological hazards. Chinese farmers must rely on heavy use of *fertilizers* to get production out of intensively cultivated soils. Chinese farmers also use many highly toxic *pesticides*. Some farmers have scant understanding of correct chemical use. They may harvest immediately after applying a pesticide, which results in excessive residues in the harvested product. *Antibiotics* are widely used to control disease in livestock, poultry, and aquaculture products. Industrialisation and lax environmental controls have also led to

⁸⁰² Since the 1990s, China has been an important exporter of food products such as vegetables, apples, shrimp, and poultry. However, China has recently had problems with food export because Chinese food has failed to meet stringent food safety standards in Japan, Europe, and other countries. Also Chinese consumers are more and more interested in food safety because of some domestic food contamination scandals.

⁸⁰³ Chinese food must meet the international food safety standards, and the increased costs of achieving these standards might have an effect on growth of Chinese food exports. Chinese foods have been rejected because of excessive antibiotic residues (EU rejected shrimp 2001, EU and Japan rejected poultry 2001, and EU rejected honey 2002), excessive pesticide residues (Japan rejected frozen spinach in 2002-2003, EU and Japan rejected tea 2002) and parasites (South Korea rejected fermented cabbage in 2005). Calvin et al. 2006, 18. News reports of product rejects compiled by USDA, Economic Research Service.

⁸⁰⁴ Calvin et al. 2006, 17.

⁸⁰⁵ Li 2005, 30.

⁸⁰⁶ Li 2005, 30.

concern about *heavy metals* in food products. Untreated human and animal waste in fields and water raises the risk of *microbial contamination*.⁸⁰⁷

The Chinese system of *food marketing* is another challenge to safety monitoring supervision. Millions of Chinese small food businesses often keep no record of what they buy and sell. In Europe, traceability of foods in the food chain is one of the key principles. Ensuring traceability is more difficult when there are millions of growers and buyers dealing with small volumes, as in China.⁸⁰⁸ The Chinese food companies are now promoting approaches to gain greater vertical control over the food chain.⁸⁰⁹

The Chinese Government aims at building a food safety system for exports that will establish China's international reputation for producing safe food. China has also been raising domestic food safety standards and implementing inspection and testing systems for consumer products and agricultural commodities. In 2005, officials announced plans to update a 1995 law covering consumer food products. In 2006, the Chinese legislature adopted a law that establishes a national framework for building a system that ensures the safety and monitoring of agricultural products. Local governments have also been active in promoting safer food.⁸¹⁰ According to Article 70 of the 2009 Food Safety Law, the State Council is responsible for formulating emergency plans for national food safety incidents. The primary actor responsible for preventing the food incident from spreading is naturally the organisation where an incident occurs⁸¹¹.

This increased weight on food safety is due to several serious food scandals where dozens of people have died. This has prompted a wave of new regulations and clean-up campaigns from the central government⁸¹². The focus on food safety includes harsh punishments for those breaking the laws. For example Zheng Xiaoyu, former head of the State Food and Drug Administration, was sentenced to the death penalty in May 2007 on charges of taking bribes and dereliction of duty⁸¹³.

According to Huang, food safety has improved in recent years thanks to measures taken by the government to enhance supervision. The general situation of food security concerning vegetables, meat, grains, fruits, dairy products, aquatic products and other food is healthier. However, supervision over food security is still weak in suburbs and rural areas, and about 8 percent of domestic food cannot reach the national food safety standards.⁸¹⁴ China will need equally severe food safety control for its domestic consumers than it already has in place for exports. The milk scandal of September 2008 shows that China still has a long way to go.

⁸⁰⁷ Calvin et al. 2006, 18.

⁸⁰⁸ Calvin et al. 2006, 18.

⁸⁰⁹ Firms have used a model in which the company leases land and controls production directly, and a model in which they use production contracts with growers that specify chemical use and production methods. Good agricultural practices (GAPs) and use of a type of Hazard Analysis and Critical Control Point (HACCP) are promoted. Calvin et al. 2006, 19.

⁸¹⁰ Calvin et al. 2006, 20.

⁸¹¹ Food Safety Law of 2009, Article 71.

⁸¹² Reuters AlertNet. <http://www.alertnet.org/thenews/newsdesk/PEK337799.htm>.

⁸¹³ China Today web page. <http://www.chinatoday.com/law/a.htm>.

⁸¹⁴ Huang Hai, assistant minister of commerce. July 19 2005. Press conference reported by China Internet Information Centre.

4.2.2.2 General Safety Requirements of Foods

In China, the Food Hygiene Law of the People's Republic of China⁸¹⁵ was enacted for the purpose of ensuring food hygiene, preventing food contamination and harmful substances from injuring human health, safeguarding the health of the people and improving their physical fitness.⁸¹⁶ The Food Hygiene Law was in 2009 replaced by the Food Safety Law. The implementing regulation of the Food Safety Law was also published in 2009. The safety of primary agricultural products is under the Law of the People's Republic of China on Quality of Agricultural Products.

The Food Hygiene Law had nine chapters:
Chapter One: General provisions
Chapter Two: Food hygiene
Chapter Three: Hygiene of food additives
Chapter Four: Hygiene of food contact materials
Chapter Five: Formulation of food hygiene standards
Chapter Six: Food hygiene control
Chapter Seven: Food hygiene supervision
Chapter Eight: Legal responsibility
Chapter Nine: Supplementary provisions.⁸¹⁷

The new Food Safety law has ten Chapters:

Chapter One: General Provisions
Chapter Two: Surveillance and Assessment of Food Safety Risks
Chapter Three: Food Safety Standards
Chapter Four: Food Production and Trade
Chapter Five: Inspection and Testing of Food
Chapter Six: Food Import and Export
Chapter Seven: Response to Food Safety Incidents
Chapter Eight: Supervision and Administration
Chapter Nine: Legal Liabilities
Chapter Ten: Supplementary Provisions

The new law is more comprehensive in detailing who is responsible for what, focusing on the critical points where there have been problems in the past. The main structure and content of the two laws are similar, though. We discuss both laws here, as the principles of the former law have been transferred into the new one.

According to Article 6 of the Food Hygiene Law of 1995, *food shall be non-toxic and harmless, conform to proper nutritive requirements and have appropriate sensory properties such as colour,*

⁸¹⁵ Passed in the 16th conference of the 8th national congress in Oct.30, 1995, and announced as No.59 Chairman Order, and implemented since the date of announcement.

⁸¹⁶ Article 1.

⁸¹⁷ Kan – Zhang 2002.

fragrance and taste. According to Article 7, foods intended specially for infants and preschool children shall conform to their specific nutritive and hygienic standards promulgated by the administrative department of public health under the State Council.

Article 8 of the Food Hygiene Law listed the hygiene requirements for food production and marketing. These were very similar to the ones in the EU hygiene legislation. They included organising clean and tidy food production facilities, the water used, disinfectants, toilets, sewage and garbage, washing hands, clean work clothes. They included also rules on clean tableware, safe storage and transportation, and clean packaging materials. The Chinese hygiene rules are more precise than the European ones and picture the different situation and tradition of food production and marketing. The Chinese hygiene rules are of the type: “measures shall be taken to eliminate flies, rodents, cockroaches and other harmful insects and to remove conditions for their propagation”.

Article 8 of the Food Hygiene Law contained a reference to local, more specific norms: “The hygienic requirements for food production or marketing undertaken by food vendors and persons engaged in the food business in urban and rural markets shall be formulated specifically according to this Law by the standing committees of the people’s congresses in the provinces, autonomous regions, or municipalities directly under the Central Government.” This Article has been considered problematic. The delegation of more specific food hygiene legislation to local legislators has led to inconsistent standards and confusing licensing requirements⁸¹⁸.

According to Article 9 of the Food Hygiene Law, the production and marketing of foods in the following categories shall be prohibited:

- 1) foods that can be injurious to human health because they are putrid or deteriorated, spoiled by rancid oil or fat, moulded, infested with insects or worms, contaminated, contain foreign matter or manifest other abnormalities in sensory properties;
- 2) foods that contain or are contaminated by toxic or deleterious substances and can thus be injurious to human health;
- 3) foods that contain pathogenic parasites, microorganisms or an amount of microbial toxin exceeding the tolerance prescribed by the State;
- 4) meat and meat products that have not been inspected by the veterinary health service or have failed to pass such inspection;
- 5) poultry, livestock, game and aquatic animals that have died from disease, poisoning or some unknown cause, as well as products made from them;
- 6) foods contaminated by use of filthy or seriously damaged containers or packages, or filthy means of conveyance;
- 7) *foods that impair nutrition or health* because they are adulterated or misbranded;
- 8) foods processed with non-food raw materials; foods mixed with non- food chemical substances, or non-food stuffs used as food;
- 9) foods that have expired the date for guaranteed quality;
- 10) foods of which the sale has been specifically prohibited, for the prevention of diseases or other special reasons, by the administrative department of public health under the State Council or by the people’s governments of the provinces, autonomous regions, or municipalities directly under the Central Government;

⁸¹⁸ Li 2005, 29.

- 11) foods that contain additives not approved for use by the administrative department of public health under the State Council or residues of pesticides exceeding the tolerance prescribed by the State; and
- 12) other foods that do not conform to the standards and requirements for food hygiene.

According to Article 10 of the Food Hygiene Law and Article 50 of the Food Safety Law, food must not contain medicinal substances, with the exception of those materials that have traditionally served as both food and medicines and are used as raw materials, condiments or nutrition fortifiers. This means medicinal plants can be used as food. They will not be classified as medicines requiring a product licence just because they contain a medicinal substance. The same plant can be used as nutrition for healthy people and as medicine for sick people.

4.2.2.3 *Biological and Chemical Safety Issues*

In China, besides the former Food Hygiene Law or the current Food Safety Law, there are a number of lower level decrees on particular *biological safety* issues on different types of products. These are, for example, separate regulations giving specific hygiene rules on food irradiation, meat and meat products, milk and milk products, eggs and egg products, aquatic products, condiments, sugar, alcohol, grain, edible vegetable oil, tea, edible mushrooms, street food, student food etc.⁸¹⁹

Chinese food safety efforts at the farm level are primarily concerned with chemical residues in spite of the fact that food poisonings and deaths from microbial contamination exceed those from farm chemical exposure. China is developing good agricultural practice guidelines, ChinaGAPs, which will address minimising the risk of microbial contamination.⁸²⁰

The *Ministry of Agriculture* is the lead agency promoting food safety at farm level. The ministry has created standards intended to guarantee that foods are free of contaminants. The “*pollution-free programme*” and the “*green food programme*” have standards specifying tolerances for harmful materials in soil, water, and air.⁸²¹ They also regulate the use of fertilisers and pesticides, and set maximum residue levels. The programs include certified production areas and trademarked symbols for use on consumer products. Packaged products carry information on the firm, which is a step towards a traceability system. Compliance is enforced by regular testing of soil, water, and air, and random testing of final products for residues.⁸²²

The above-mentioned programs are voluntary, and not yet commonly followed. In 2005, about 6 percent of the volume of agricultural production met the pollution free standard, and 1 percent the green standard, which is stricter.⁸²³ The decision to produce green or pollution-free food is usually made by local officials or agribusiness enterprises, not the individual farmers⁸²⁴. The trend is inevitably towards green food, though. This is because exports require

⁸¹⁹ Kan – Zhang 2002.

⁸²⁰ Calvin et al. 2006, 20-21.

⁸²¹ More specifically, the green food program defines two categories of green food. AA green food is equal to organic food, and A green food is between normal food and organic food. A green food is more realistic in China, as Chinese land is already heavily polluted. GMOs can be used in A but not AA green food.

⁸²² Calvin et al. 2006, 20.

⁸²³ Calvin et al. 2006, 20.

⁸²⁴ Calvin et al. 2006, 21.

adherence to rather strict rules, and also because Chinese consumers are becoming more aware and cautious. Bian sees green food as a suitable compromise between organic food and normal food, particularly for developing countries. Following the green food standard does not make food too expensive, but use of fertilisers and pesticides is still heavily restricted.

Besides regulations on contaminants and residues, chemical safety is the goal of regulations on *food additives*⁸²⁵ and *food contact materials*⁸²⁶. In Chinese law, “food additive” refers to any synthetic compound or natural substance put into food to improve its quality, colour, fragrance or taste, or for the sake of preservation or processing. “Nutrition fortifier” refers to any natural or artificial food additive belonging to the category of natural nutrients that is put into food to increase its nutritive value.⁸²⁷

According to Article 11 of the Food Hygiene Law, the production, marketing and use of food additives must conform to the hygiene standards for use of food additives and the hygiene control regulations. Food additives that do not conform to the hygiene standards and the hygiene control regulations may not be marketed and used. Specific standards on additives are given by the 2002 “Administrative Provisions for Food Additive Hygiene”⁸²⁸.

In 2005, Chinese government organisations announced that food additives constitute the greatest threat to food safety in China. To address this problem, authorities promised to increase the number of quality specifications of food additives in line with global standards. In 2005, less than a quarter of all state quality specifications for food additives can be compared with international standards. The government promised to increase this ratio to at least a half by 2007.⁸²⁹

Food contact materials were regulated by Articles 12 and 13 of the Food Hygiene Law: “Containers, packaging, utensils and equipment used for food must conform to the hygiene standards and the hygiene control regulations. The raw materials for making containers, packaging, utensils and equipment used for food must meet hygiene requirements. The finished products should be easy to clean and disinfect. According to AP-Foodtechnology.com, the new Food Safety Law has already boosted food packaging business in China. The law has created demand for “coated materials with barriers designed to keep bacteria out and freshness in the package”⁸³⁰.

4.2.2.4 Safety of Health Foods: Raw Materials

Functional foods, fortified foods, and vitamin and mineral supplements are in China regulated as health foods. Health foods are *foods which have a specific health function, are suitable for a certain group of people, and which are not for therapeutic purposes*. Requirements on health food safety and efficacy are here discussed separately, even though these two aspects are in China evaluated in a single procedure. Health food efficacy and claims are discussed in chapter

⁸²⁵ In 2002, 431 varieties of food additives and 1040 varieties of spices had been approved by the Ministry of Health. Kan – Zhang 2002.

⁸²⁶ Kan – Zhang 2002.

⁸²⁷ Chinese Food Hygiene Law, Article 54: Definitions.

⁸²⁸ MOH regulation; Order No. 26; Promulgation Date: 2002-03-28; Effective Date: 2002-03-28.

⁸²⁹ Functional Ingredients March 2005. China News.

⁸³⁰ News article at ap-foodtechnology.com, by Rory Harrington 20 October 2009.

5. Procedural rules on health foods (concerning the pre-market authorisation procedure) were discussed above in chapter 2.

The legal basis for Chinese health food regulations was formerly in Articles 22 and 23 of the Chinese Food Hygiene Law. In Article 22 of the Chinese Food Hygiene Law, it refers to specific rules on health foods: “With regard to food indicated to have specific health functions, the product and its description must be submitted to the administrative department of public health under the State Council for examination and approval. Hygiene standards and control measures for the production and marketing of the product are then formulated by the authority.” According to Article 23 of the Food Hygiene Law, the food claiming to have specific health functions may not be harmful for human health. The content of the product manual shall be accurate and truthful while the functions and ingredients of the product shall be identical with the marketing claims.⁸³¹

The new Food Safety Law states the same rules on health foods in its Article 51. It is first stated, “the state executes strict regulations on health foods”. Health foods may not pose acute, sub-acute or chronic hazard to the human body. Labels and instructions may not refer to disease treatment or prevention, all information and claims must be truthful, and the product must comply with the information.

The Health Food Regulation of 1996⁸³² and its subsequent amendments give more precise rules on health foods. The Health Food Regulation was enacted to strengthen the administration and supervision of health foods, ensuring the quality of health foods according to the Food Hygiene Law⁸³³. The regulations focus on evaluation and approval of health foods, and are as such directed more at authorities than at entrepreneurs. However, there are also sections regulating production and marketing of health foods.

The regulations establish minimum safety and efficacy requirements for health foods as follows:

- raw materials and final products must comply with food hygiene requirements and shall not cause any acute, sub chronic, or chronic harm to human body,
- necessary animal and/or human tests must have confirmed a clear and stable health effect,
- formulation and dosage must be based on scientific evidence (the functional ingredient should be identified but when that is impossible, at least the raw materials that cause the effect shall be listed),
- therapeutic effects shall not be claimed in labelling or advertising.⁸³⁴

In addition to general hygiene rules, *safety of health foods is controlled via controlling the choice of raw materials*. A separate Notification from 2002⁸³⁵ governs the raw materials of health foods. First of all, the Notification aims to clear the situation of overlapping pieces of legislation. Novel foods are considered a separate issue from health foods. If a health food has novel ingredients, the Novel Food Regulation shall be followed. Further, if the health

⁸³¹ Article 23 of the Chinese Food Hygiene Law.

⁸³² Ministry of Health: Administrative Regulations on Health Food, Order No. 46 (Promulgation Date: 1996-03-15; Effective Date: 1996-06-01.)

⁸³³ Article 1.

⁸³⁴ Health Food Regulation, Article 4. Huang – Lapsley 2005, 266.

⁸³⁵ Ministry of Health: Notification on Further Standardising the Management of Raw Materials for Health Food (Directive, Document No.:WeiFaJian[2002]51, Promulgation Date: 2002-02-28.

food uses food additives, additive law applies. Additionally, there are particular rules on fungal health foods⁸³⁶, probiotic health foods⁸³⁷, and nuclei acid type of health foods⁸³⁸. These products should follow these procedures respectively.⁸³⁹

If health foods involve protected wild animals or plants, they should be applied according to Notification of Restraining the Produce of Health Food using Wild Animal and Plants as Raw Materials of Ministry of Public Health of the Notification of 5th July 2001 restraining the use of certain single materials⁸⁴⁰ that have anti-desert function in the wild.⁸⁴¹

Other health food raw materials are regulated by three lists given by the Annexes of the Health Food Raw Material Regulation:

- List I includes materials that can be used either as foods or medicines.
- List II includes materials that can be used as health food materials.
- List III includes materials that are prohibited as health food materials.

The more complicated rules are given by point 5 of the Raw Material Notification:

- First of all, if health foods involve products (or materials) of animals or plants, the number of products (or materials) of animals or plants can not exceed 14.
- If health foods use products (or materials) that are not listed in the List of Materials which are used as either Foods or Medicines, the number of products or materials of animals or plants cannot exceed 4.

⁸³⁶ Regulation on Evaluation and Examination of Fungal Health Foods, valid from March 23rd 2001. Fungal health food means food with specific health function, which uses edible macro-fungi and carpophores and filaments or filament macro-fungi. Fungal health food must be safe and dependable, i.e. safe for eating, non-toxic and not harmful. The strains used in production must have clear and stable characteristics of biology, genetics and functionality. Article 3. Only certain fungus species are permitted as health food ingredients. The permitted fungus species are the following: *Saccharomyces cerevisiae*, *Candida atilis*, *Kluyveromyces lactis*, *Saccharomyces carlsbergensis*, *Paecilomyces hepiali* Chen et Dai, sp. Nov, *Hirsutella hepiali* Chen et Shen, *Ganoderma lucidum*, *Ganoderma sinensis*, *Ganoderma tsugae*, *Monascus anka*, *Monascus purpures*. Huang – Lapsley 2005, 266. If an entrepreneur wants a fungus to be added on the list, an application to the SFDA has to be made.

⁸³⁷ Regulation on Evaluation and Examination of Probiotic Health Foods, valid from March 23rd 2001. Probiotic health food means preparation which promotes ecological balance of bacterial colony in the intestine and is beneficial to human health. Article 2. The probiotic strains must belong to one of the normal bacterial colonies in human body. It is allowed to use live or dead bacteria and bacterial metabolites. The probiotic health food must be safe and dependable, i.e. safe for eating with no adverse reactions. The strains used in production must have clear and stable characteristics of biology, genetics and functionality. Only certain probiotic bacteria are allowed as health food raw materials. The permitted probiotics are the following: *Bifidobacterium bifidum*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Bifidobacterium breve*, *Bifidobacterium adolescentis*, *Lactobacillus bulgarius*, *Lactobacillus acidophilus*, *Lactobacillus casei* subsp. *Casei*, *Streptococcus thermophilus*. Huang – Lapsley 2005, 266. If an entrepreneur wants a probiotic to be added on the list, an application to the SFDA has to be made.

⁸³⁸ This means health foods using DNA or RNA as raw material. The purity of DNA or RNA must be above 80 percent, and the recommended dosage for nuclei health foods should be 0,6g-1,2g per day. Huang – Lapsley 2005, 266.

⁸³⁹ Points 1, 2, and 3 of the Notification.

⁸⁴⁰ Wild liquorice, saussurea involucrate, xxx and xxx. There is no English word for the latter two.

⁸⁴¹ Point 4 of the Notification.

- If health foods use products (or materials) of animals or plants not listed in the List of Materials, which are used as either Foods or Medicines *and neither in* List of Materials, which can be used in Health Foods, the number of products (or materials) of animals or plants can not exceed 1. This product (or material) of animal or plant should go through safety and toxicology evaluation according to the Novel Food Regulation.

If you want to use a material outside both lists, you can only use one which cannot be on the third list of forbidden materials. If you wish to use materials on the first and the second list or merely on the second list, you can use four materials altogether. If you can settle with the materials listed in the first list, then you can have 14 materials. Normal food materials are not included in this number, only materials with health effects.

Category I includes approximately 90 materials, for example Hawthorn fruit (*Fructus Crataegi*), Barbary wolfberry fruit (*Fructus Lycii*), Lotus leaf (*Folium Nelumbilis*), Lotus seed (*Semen Nelumbilis*), Hemp seed (*Fructus Cannabis*), Ginkgo seed (*Semen Ginkgo*), Oyster Shell (*Concha Ostreae*), Honey (*Apis Melifera*), Peppermint (*Herba Menthae*), Peach seed (*Semen Persicae*), and Tangerine peel (*Citrus Reticulata*).⁸⁴²

Some of the products containing these materials will be classified as traditional medicines. Whether a product is a health food or a traditional medicine will depend on functions and marketing claims of the product. See the separation of foodstuffs and medicines above in section 3.

Category II includes approximately 110 materials, for example Ginseng root, leaf and fruit (*Radix Ginseng*, *Folium Ginseng*, *Fructus Ginseng*), Deer embryo (*Fetus Cervi*), Deer bone (*Fel Cervi*), White peony root (*Radix Paeoniae alba*), Red peony root (*Radix Paeoniae rubra*), Aloe vera (*Herba aloe*), Magnolia flower (*Flos magnoliae*), Tortoise shell (*Carapax et Plastrum testudinis*), and Ginkgo leaf (*Folium Ginkgo*).⁸⁴³

Category III includes approximately 60 materials, for example Poppy capsule (*Pericarpium Papaveris*), Quicksilver (Mercury), Chinese azalea flower (*Flos Rhododendri mollis*), Lily of the valley grass (*Herba Convallariae majalis*), Mung bean blister beetle (*Lytta Caraganae pallas*), and Blowfish (Globefish, *Tetraodontiforms syn. Plectognathi*).⁸⁴⁴

In addition to complying with the lists, the product must pass a *toxicological safety assessment*. There is a Ministry of Health standard⁸⁴⁵ establishing requirements for toxicological testing. Animal test requirements vary from no need for toxicological testing to four tiers of tests (tier I: acute toxicity; tier II: genetic toxicity; tier III: sub-chronic toxicity; tier IV: chronic toxicity).⁸⁴⁶

The test requirements depend on the categories of the raw materials. If the product is made of *common foods and Category I ingredients*, and processing and consumption of the food are traditional, no tests are required on raw material of finished products. However, if the product is processed and consumed so that dosage is greater than normal, tests are needed on final products. For foods made of *category II ingredients*, tests on the final product are always needed. For those

⁸⁴² See complete list by Huang – Lapsley 2005, 267-269.

⁸⁴³ See complete list by Huang – Lapsley 2005, 269-272.

⁸⁴⁴ See complete list by Huang – Lapsley 2005, 272-274.

⁸⁴⁵ Ministry of Health: Technical Standards for Testing and Assessment of Health Food. Promulgation date 14 February 2003, effective 1 May 2003.

⁸⁴⁶ Huang – Lapsley 2005, 274-275.

other ingredients that are not common foods, or category I or II ingredients, tests are always needed both on the raw material and the finished product. The strictest requirements apply if the raw material has no historical human consumption data at all.⁸⁴⁷

There is no specific legislation on *food supplements* in China and food supplements thus do not form a separate legal category. The pre-market authorisation requirements depend on whether the supplement contains *vitamins, minerals, or something else*, and whether or not *health claims* are presented on the product. As stated above, only health foods are allowed to bear health claims in China. This applies to foods in food form and food supplements.

For those supplements that contain *authorised vitamins or minerals*, there is a special procedure under the Health Food Regulation. They need to obtain an “Approval Certificate for Health Food” prior to production, but clinical tests on safety and efficacy of the vitamin or mineral are not required. The producer still needs to show hygiene, stability etc. *Other supplements* such as those containing dietary fibres, proteins, or amino acids, are considered common foods where no pre-market control applies. For common foods, health claims are not allowed. If health claims are required, the supplement must undergo the whole health food process.⁸⁴⁸

4.2.2.5 *Safety of Novel Foods*

4.2.2.5.1 Definition of Novel Food

There is a new Regulation on novel foods in China⁸⁴⁹. The previous Regulation dates back to 1990. Everything that has appeared on the Chinese market since 1990 has been considered novel. The new Chinese definition of novel foods is the following⁸⁵⁰:

- (1) Animals, plants and micro-organisms that are not traditionally consumed in China;
- (2) Raw food materials that are derived from animals, plants and micro-organisms and are not traditionally consumed in China;
- (3) New varieties of micro-organisms that are used during food processing;
- (4) Raw food materials the original composition or structures of which are changed by the adoption of new techniques during production.

According to the previous definition in the 1990 law, novel foods are newly *manufactured*, newly *discovered* and newly *introduced* materials, which people are not accustomed to eating or are accustomed to eating in very local places, and meet basic requirements as food. The concept of novel food includes raw materials and final products.⁸⁵¹ The Novel Food Regulation does not cover GMO food or additives, which are regulated separately.

Novel foods must undergo a pre-market assessment by the Ministry of Health. Foods listed in Article 2 but not yet approved and published as novel foods by the Ministry of

⁸⁴⁷ Huang – Lapsley 2005, 275.

⁸⁴⁸ Huang – Lapsley 2005, 266.

⁸⁴⁹ Administrative Measures on Hygiene of Novel Foods. 2007.

⁸⁵⁰ Novel Food Regulation 2007, Article 2.

⁸⁵¹ Novel Food Regulation 1990, Article 2.

Health shall not be manufactured, operated or used as food or raw food materials⁸⁵². A producer must himself evaluate whether his food product is novel. The Ministry of Health will make the decision once it has received and reviewed a novel food application, and inform the applicant if the novel food is considered a regular food⁸⁵³. This means novel food evaluation starts by evaluating whether the food is in fact novel. The Ministry of Health will publish *a list of products that have been considered regular foods*⁸⁵⁴, and this list will help later applicants in determining whether an application is necessary.

A consumer will recognise a novel food from labelling: “Novel foods or food products containing novel foods shall be labelled in compliance with relevant government regulations and names indicated in the labels shall be identical to that announced by the Ministry of Health.”⁸⁵⁵

As the new regulation came into force, there were some 340 novel foods on the market. These may be reviewed to comply with the new rules. An example of a novel food authorised according to the previous regulation is the sugar replacement Isomalt, made by Palatinit. It was the first non-Chinese food to pass the Chinese Novel Food approval process set by the Ministry of Health in September 2006. The approval allows Isomalt to be labelled as a “New Resource Food” instead of just an “additive”. The producer believes this will make the ingredient more attractive to food makers and that the novel food status will help to differentiate the ingredient from similar products on the market. Palatinit claims that most other polyols have been approved under the food additive standard. The novel food standard is perceived as more difficult but potentially more valuable.⁸⁵⁶

4.2.2.5.2 Safety Requirements of a Novel Food

According to Article 5 of the Novel Food Regulation, “Novel food shall comply with the Food Hygiene Law of the People’s Republic of China, pertinent regulations, rules and standards, and *shall not cause any acute, sub acute, chronic or other latent health hazards*”. Food safety is the very goal of novel food legislation, and because the food is novel, safety of long-term use in particular is not easily determined. Food safety assessment of novel food shall follow the principles such as *risk assessment* and *substantial equivalence*⁸⁵⁷. Risk assessment refers to “scientific evaluations on known or potential negative effects of food borne hazards which human body exposes to upon human health, including four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation”⁸⁵⁸. The doctrine of substantial equivalence means that to avoid unnecessary or duplicative research efforts, essential similarity to traditional or already authorised products is used as proof of safety.

The Ministry of Health has an Expert Assessment Committee on Novel Foods that is responsible for safety assessment of novel food. The Assessment Committee is composed of experts in fields of food hygiene, toxicology, nutrition, micro organisms, processing

⁸⁵² Novel Food Regulation 2007, Article 18.

⁸⁵³ Novel Food Regulation 2007, Article 13.

⁸⁵⁴ Novel Food Regulation 2007, Article 15.

⁸⁵⁵ Novel Food Regulation 2007, Article 22.

⁸⁵⁶ AP-foodtechnology.com. News 26/09/2006.

⁸⁵⁷ Novel Food Regulation 2007, Article 6.

⁸⁵⁸ Novel Food Regulation 2007, Article 28.

techniques, chemistry, pharmacology, etc.⁸⁵⁹ The Assessment Committee shall exercise its safety assessment on the basis of the following materials and data:

- source of novel food,
- traditional consumption history,
- processing techniques,
- quality standards,
- main ingredients and contents,
- estimated intake,
- usage and scope of application,
- toxicology,
- biological features,
- genetic stability,
- pathogenicity and toxicity of strains of microbiological products, and
- other scientific data.⁸⁶⁰

The Ministry of Health may reassess an approved novel food in any of the following circumstances:

- (1) With the development of science and technology, recognition of food safety and nutrition about approved novel food has changed;
- (2) Challenges raised against food safety and nutritional quality of novel food;
- (3) As required by supervision and monitoring of novel food.

If the approved novel food fails to pass the reassessment, the Ministry of Health may announce prohibition on production, business operation and use of the food.⁸⁶¹

The Chinese criteria for establishing novel food safety are similar to the European legislation. The nutritional aspect of safety is relevant in China in a manner similar to the European approach. Safety of a novel food is not regarded as such but rather as part of the diet where the novel food replaces another food. In addition to the Chinese Novel Food Regulation, there will be further, more precise, regulations on novel foods: “Ministry of Health formulates and promulgates safety assessment regulations, technical specifications and standards of novel food”.⁸⁶² One can expect a similar puzzle of regulations as with Health Foods. It would be simpler if regulation targets could read the novel food regulations in one piece of law.

4.2.2.5.3 Decisions or Regulations?

According to the Chinese Novel Food Regulation, the Ministry of Health publishes the list of approved novel foods, which, based on characteristics of different novel foods, should cover contents such as:

⁸⁵⁹ Novel Food Regulation 2007, Article 7.

⁸⁶⁰ Novel Food Regulation 2007, Article 8.

⁸⁶¹ Novel Food Regulation 2007, Article 9.

⁸⁶² Novel Food Regulation 2007, Article 6.

- generic name (including Latin name),
- species,
- source,
- biological characteristics,
- adopted techniques,
- main ingredients,
- edible parts,
- dosage level,
- scope of application,
- ethnical group of application,
- intake amount,
- and quality standards;
- for micro organisms, their strain numbers⁸⁶³ shall also be indicated.⁸⁶⁴

According to Article 20 of the Novel Food Regulation, “Food manufacturers shall verify the Ministry of Health’s announcement and *make sure their products are substantially equivalent* with the announced items before they start manufacturing or using the novel food.” This means the list of approved novel foods will serve other operators as proof of established safety. The operators need not repeat the novel food application. Substantial equivalence is defined in Article 28 of the Regulation:

“Substantial equivalence: means that if raw materials or food ingredients of a novel food are substantially equivalent to *traditional food* or food ingredients or *approved novel food* in terms of species, source, biological characteristics, main ingredients, edible parts, dosage level, scope of application and group of application, and their processing techniques and quality standards adopted are basically identical, the novel food is considered equally safe as the traditional counterpart and has substantial equivalence.”

This means that in China, a food is legally equivalent to traditional foods if a previously authorised substantially equivalent novel food exists. In Europe, the same situation at the moment calls for a notification. For example Noni fruit was first in Europe authorised as a novel food in 2002, after which it has been notified dozens of times. As described above, discussions on the property nature of the novel food authorisation have been ongoing in Europe. It has been proposed that instead of decisions, novel food authorisations should be given as regulations applicable to all operators. The efforts of the applicant would in this case be rewarded by granting a period of exclusivity to the research data on safety.

⁸⁶³ According to freedictionary.com, strain means “a group of organisms of the same species, having distinctive characteristics but not usually considered a separate breed or variety”. For example with probiotics, safety and functionality are strain dependent, and genus, species, and strain number are often given in labelling. Coueret et al. 2004.

⁸⁶⁴ Novel Food Regulation 2007, Article 14.

4.2.2.6 Safety of Genetically Modified Foods

Chinese GMO legislation has existed since the early 1990s, and been developed since. However, a Regulation on the Hygiene of GMO Foodstuffs was not enacted until 2002⁸⁶⁵. GMO foods were regarded as normal food before 2002. According to Bian, Chinese legislation on GMOs foods has been practical and responded simply to the need for food. Increasing amounts of GMO food are imported into China, particularly soybeans, especially from the United States. Academia or the public have not been consulted in GM issues or their regulation.⁸⁶⁶

There are five major government agencies that oversee GMOs in China.⁸⁶⁷ This inevitably leads to a situation where the farm to table -approach is not fulfilled, and overlap and conflict is bound to happen. For agricultural GMOs that are intended for use as *raw materials*, importers must apply for an agricultural GMO safety certificate from the Ministry of Agriculture. The Ministry of Health is primarily responsible for regulating GMO food.⁸⁶⁸ Foreigners intending to export *finished GMO food* to China will need to apply for a safety certificate from the Ministry of Health. The application must include an assessment report on GM food safety and its nutritional quality, produced by a testing agency accredited by the Ministry of Health. In addition, the exporter must show documents to prove that the GMO food has been approved for use in the exporting country.⁸⁶⁹

Under the GMO Food Regulation, all foods made from animals, plants or micro organisms, whose genome composition is modified through biotechnology, need to undergo a safety assessment and approval process. The *GMO Food Expert Committee* established by the Ministry of Health carries out the safety assessment, within 6 months of receiving an application⁸⁷⁰. The

⁸⁶⁵ Administrative Measures on Hygiene of GMO Foodstuffs, Regulation No. 28 (2002) of the Ministry of Health, was issued on 8 April 2002. Other GMO regulation includes:

- Regulations on Genetic Engineering Management, Regulation No. 17 (1993) of the State Commission of Science and Technology.
- Regulations on Safety Control of Agricultural Genetically Modified Organisms, Regulation No. 304 (2001) of the State Council.
- Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms, Regulation no. 8 (2002) of the Ministry of Agriculture, issued on 5 January 2002.
- Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms, Regulation no. 9 (2002) of the Ministry of Agriculture, issued on 5 January 2002.
- Implementation Regulations on Labelling of Agricultural Genetically Modified Organisms, Regulation No. 10 (2002) of the Ministry of Agriculture, issued on 5 January 2002.

⁸⁶⁶ Bian 2004. China imported 11.3 million tons of soy already in 2002, and imports were increasing.

⁸⁶⁷ They are: the Ministry of Science and Technology, the Ministry of Agriculture, the Ministry of Health, the State Environmental Protection Administration, and the General Administration for Quality Supervision and Inspection and Quarantine. MOST is responsible for national research and development of science and technology. It is the competent authority responsible for genetic engineering. Each process of genetic engineering (research and experimentation, field testing, pre-market production testing etc.) is subject to safety assessment and safety control measures. The National Genetic Engineering Safety Committee supervises and coordinates these activities. Wanhua 2003, 99. The Ministry of Agriculture (MOA) is in charge of agricultural GMO Regulation. Wanhua 2003, 100. SEPA is responsible for China's environmental protection and biodiversity conservation. Wanhua 2003, 100. AQSIQ is the Chinese customs office. The Ministry of Foreign Trade and Economic Cooperation (MOFTEC) is also involved in formulating GMO regulations. Wanhua 2003, 101.

⁸⁶⁸ Wanhua 2003, 100.

⁸⁶⁹ Wanhua 2003, 106.

⁸⁷⁰ Wanhua 2003, 105.

safety assessment includes nutrition assessment. Also unanticipated effects must be taken into account.⁸⁷¹ The Ministry of Health administers the list of authorised GMO foods. GMO food must also be labelled as such, see chapter 5.

Critics claim that China's control of GMO use in agriculture is poor. For example in 2005, it was discovered that illegal genetically modified rice was being grown and sold in a Chinese province⁸⁷². The GMO Food Regulation makes the Ministry of Health responsible for inspections, but does not specify how these control activities shall be carried out. Chinese GMO regulations are still under development, and China ratified the Cartagena Protocol on Biosafety⁸⁷³ in 2005. China's adherence to international agreements is important, as China is potentially the largest GMO producer and consumer⁸⁷⁴ in the world.⁸⁷⁵

4.3 Medicine Safety

4.3.1 EU: Different Categories of Medicinal Products

In Europe, safety and efficacy requirements for human medicines are governed by directive 83/2004/EC. Besides provisions applicable to all medicinal products, there are specific provisions for:

- herbal medicinal products,
- traditional herbal medicinal products,
- homeopathic medicinal products,
- immunological medicinal products⁸⁷⁶,
- radiopharmaceuticals⁸⁷⁷, and
- medicinal products based on human blood or human plasma.

Particular provisions on immunological medicinal products, radiopharmaceuticals, and medicinal products based on human blood or human plasma are not discussed here.

⁸⁷¹ Wanhua 2003, 100.

⁸⁷² China Internet Information Centre. http://service.china.org.cn/link/wcm/Show_Text?info_id=149812&p_qry=gmo.

⁸⁷³ A global protocol that aims to regulate international trade of GMOs. The Cartagena Protocol on Biosafety is part of the Convention on Biological Diversity. <http://www.cee-foodindustry.com/news/ng.asp?n=60140-gmo-issues-step>.

⁸⁷⁴ For example in 2006, China imported 28.27 million tons of soybeans, a historical high. Most of them were GM-soybeans. Soyatech web page: http://www.soyatech.com/news_story.php?id=1725.

⁸⁷⁵ Wanhua 2003, 107-108.

⁸⁷⁶ 'Immunological medicinal product' means any medicinal product consisting of vaccines, toxins, serums or allergen products. Directive 83/2001/EC, Article 1.4.

⁸⁷⁷ 'Radiopharmaceutical' means any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose. Directive 83/2001/EC, Article 1.6.

4.3.1.1 Modern Medicines⁸⁷⁸

Here we discuss the substantial safety criteria for medicines. The pre-market authorisation procedures for medicines were discussed above in chapter 2.

According to Regulation 726/2004/EC⁸⁷⁹, “in the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the *objective scientific criteria of quality, safety and efficacy* of the medicinal product concerned, *to the exclusion of economic and other considerations*”. However, Member States can exceptionally prohibit the use in their territory of medicinal products for human use, which “infringe objectively defined concepts of public policy and public morality”⁸⁸⁰.

Authorisation shall be refused for products that are *harmful* in the normal conditions of use⁸⁸¹. According to Directive 2001/83/EC⁸⁸², the concepts of *harmfulness and therapeutic efficacy can only be examined in relation to each other*. Safety and efficacy are relative concepts depending on the progress of scientific knowledge and the use for which the medicinal product is intended. With medicines, the *potential risks must be outweighed by the therapeutic efficacy* of the product.⁸⁸³ Substantial safety criteria as such are not given in the legislation. The authorities must weigh the evidence on safety vs. efficacy on a case-by-case basis. Safety of medicines is thus primarily controlled via the *standards on tests and trials* that must be performed⁸⁸⁴.

Another means to guarantee safety is to grant authorisations subject to *conditions* that are considered essential for the safe and effective use of the medicinal product⁸⁸⁵. These conditions include *pharmacovigilance*, which means that the authorisation holder must monitor, scientifically evaluate, and report the effects of the medicinal product. Also, doctors are required to report suspected adverse reactions. The renewal of a product licence relies particularly on data on Pharmacovigilance⁸⁸⁶.

Medicine safety is also always related to *information* given in marketing: there are strict requirements on the mandatory information that must be given to prescribed users to guarantee safe use of medicines. This information includes contraindications, instructions on proper use of the product, dosage, interactions with other products, etc. Marketing rules will be discussed below in chapter 5.

⁸⁷⁸ ‘Modern medicine’ is not a legal term. Modern medicines are here presented as a category of medicinal products for which there are no particular provisions in the medicinal products directive, and to which the normal safety requirements and the primary procedure for medicinal products evaluation thus apply.

⁸⁷⁹ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

⁸⁸⁰ Regulation 726/2004/EC, preamble 13.

⁸⁸¹ Directive 2001/83/EC, Article 26.

⁸⁸² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

⁸⁸³ Directive 2001/83/EC, preamble 7.

⁸⁸⁴ These standards are important for public health reasons, and to enable free movement of goods.

⁸⁸⁵ Directive 2001/83, Article 32(4).

⁸⁸⁶ Directive 2001/83/EC, Article 24.

4.3.1.2 Herbal Medicinal Products

Herbal medicinal products are plant-based medicines. In the EU they are used for various health problems, for example, as cough remedies, to help circulation, to fight muscular pain, to help digestion, as cold remedies, for calming and sleeping, as laxatives, for bladder and kidneys and as remedies for the liver⁸⁸⁷.

Regulation of herbal medicines is challenging. Herbal medicine used to be the only medicine. Modern medicine was then developed and legislation created. Now that herbal medicine is gaining popularity in the West, it also has to be considered by regulators. Even though traditional medicine is available in several countries, regulation is not highly developed. Herbal medicine was probably seen as something too complex to deal with. The underlying difficulty is that a scientific understanding of traditional medicine and acceptance by the international community is not yet strong. Differences in culture, history and religion explain differing attitudes towards herbal medicine from country to country. Even finding a common language between traditional and western medicine has proven difficult.⁸⁸⁸

There are many legal questions to be answered regarding herbal medicine. First of all, there is a need to develop research protocols fit for the evaluation of the safety and efficacy of traditional medicine. Post-market surveillance systems to monitor the adverse effects must be created. There is an enormous amount of both thousands of years-old and new information that must be shared to avoid duplication of efforts. Related to information, intellectual property issues must be resolved.⁸⁸⁹

The EU definition of herbal medicinal product is in the medicinal product directive, Article 1(30):

“Herbal medicinal product: any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.”

Herbal substances are “all mainly *whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh*”. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).⁸⁹⁰

Herbal preparations are “preparations obtained by *subjecting herbal substances to treatments* such as extraction, distillation, expression, fractionation, purification, concentration

⁸⁸⁷ Germany and France dominate the European herbals market with 39 % of sales value in Germany and 29% in France. Silano et al. 2004, 108.

⁸⁸⁸ Ministry of Science and Technology web page. http://www.most.gov.cn/eng/policies/regulations/200608/t20060823_35603.htm.

⁸⁸⁹ Ministry of Science and Technology web page. http://www.most.gov.cn/eng/policies/regulations/200608/t20060823_35603.htm.

⁸⁹⁰ Medicinal products directive, Article 1(31).

or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.”⁸⁹¹

Herbal medicinal products are used both to prevent and treat diseases. They are usually used in addition to conventional treatments. They are often used in chronic conditions such as severe pain, rashes, or problems in the digestive system, and when conventional medicine cannot help. The diseases that are treated by herbal medicinal products range from minor ailments to serious diseases like cancer. There are about 1500 medicinal plants in use in Europe. The most popular ones are: ginseng (*Panax ginseng*), evening primrose (*Oenothera biennis*⁸⁹²), St. John’s Wort (*Hypericum perforatum*⁸⁹³), ginkgo (*Ginkgo biloba*⁸⁹⁴), purple Echinacea (*Echinacea sp.*⁸⁹⁵), and garlic (*Allium Sativum*).

The producer of an herbal medicinal product must have a product licence before marketing the product. In connection with the product licence, the authority assesses whether the safety and efficacy in the presented indication can be considered adequate. To guarantee the quality and safety of the product, an herbal medicinal product must be produced in an authorised facility.⁸⁹⁶

To receive a product licence, the Medicinal Products Directive⁸⁹⁷ requires that applications for authorisation to place a medicinal product on the market have to be accompanied by a complete dossier of documents. This dossier contains information relating to the results of physico-chemical, biological or microbiological tests as well as pharmacological and toxicological tests and clinical trials carried out on the product and thus proving its quality, safety and efficacy. This applies in principle to all medicinal products, if no exception is made in some other Article of the Directive.

Article 10(a) of the Directive grants this kind of a relief, which is often used by herbal medicines:

“By way of derogation from Article 8(3)(i), ..., the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been *in well-established medicinal use within the Community for at least ten years*, with recognised efficacy and an acceptable level of safety In that event, the test and trial results shall be replaced by appropriate *scientific literature*.”

Factors which have to be taken into account in order to establish a preset use of medicinal products are:

- the time over which a substance has been used,
- quantitative aspects of the use of the substance,
- the degree of scientific interest in the use of the substance (reflected in the published scientific literature), and
- the coherence of scientific assessments.⁸⁹⁸

⁸⁹¹ Medicinal product directive, Article 1(32).

⁸⁹² In Finnish: helokki.

⁸⁹³ In Finnish: mäkikuisma.

⁸⁹⁴ In Finnish: neidonhiuspuu.

⁸⁹⁵ In Finnish: punahattu.

⁸⁹⁶ Enkovaara 2002, 23.

⁸⁹⁷ Article 6.

⁸⁹⁸ Directive 2001/83/EC, Annex I, Part III: Toxicological and Pharmacological tests. II Performance of tests. I. Well-established medicinal use. Point (a).

Different periods of time may be necessary for instituting well-established use of different substances. In any case, the required period of time for instituting a well-established medicinal product is at least 10 years from the first systematic and documented use of that substance as a medicinal product in the Community.⁸⁹⁹

According to the Annex of the Medicinal Products Directive, the documentation should cover all aspects of the safety assessment. It must include a review of the relevant literature, taking into account pre- and post marketing studies and published scientific literature on epidemiological studies. Comparative *epidemiological studies* are particularly important. All documentation, both favourable and unfavourable, should be communicated. Particular attention must be paid to any *missing information* and justification must be given as to why demonstration of an acceptable level of safety can be supported although some studies are lacking. If some of the data concerning a product is different from the product intended for marketing, the applicant must explain the relevance of this data. Applicants are instructed to put a special emphasis on *post-marketing experience* with other products containing the same components.⁹⁰⁰

Applications for herbal medicinal products are usually based on review of existing literature. What is notable is that an herbal medicine not used within the Community does not benefit from the literature derogation. Herbal medicines used only in third countries must thus always go through the primary procedure including all the pre-clinical tests and clinical trials.

In Finland, most herbal medicine product licences are based on a national evaluation procedure by the National Administration for Medicines⁹⁰¹, which comes under the Ministry of Social and Health Issues. The National Agency of Medicines grants a selling permit for an herbal medicinal product, and simultaneously decides on where it can be sold. The alternatives are pharmacy, natural product store or grocery store. This decision depends on the purpose of use, possible risk factors, and need for guidance⁹⁰². Herbal medicines cannot be sold through pyramid schemes, mail, or the Internet.

4.3.1.3 Traditional Herbal Medicinal Products

As stated above, marketing of an herbal medicinal product requires an authorisation to be granted on the basis of results of tests and experimentations concerning quality, safety and efficacy. For medicinal products that are, according to adequate published data, of established use⁹⁰³, there is no need to provide safety and efficacy data.

Still, a significant number of herbal medicinal products, despite their long tradition, do not fulfil the requirements of a well-established medicinal use with recognised efficacy and an acceptable level of safety. These products are not eligible for a marketing authorisation as described above. New tests and experimentations could be carried on such products to make

⁸⁹⁹ Directive 2001/83/EC, Annex I, Part III: Toxicological and Pharmacological tests. II Performance of tests. I. Well-established medicinal use. Point (a).

⁹⁰⁰ Directive 2001/83/EC, Annex I, Part III: Toxicological and Pharmacological tests. II Performance of tests. I. Well-established medicinal use. Points (b), (c), (d), and (e).

⁹⁰¹ In Finnish: Lääkelaitos.

⁹⁰² Bäcklund 1998, 156.

⁹⁰³ In the meaning of Article 10, para 1, letter (a), point (ii) of the medicinal products directive, and as specified in Part 3 of Annex 1 of the same Directive.

it possible to authorise them under the above-mentioned procedure. However, this would be expensive and it would be difficult to justify animal tests and human clinical trials on products for which a longstanding tradition of use makes it possible to evaluate safety and efficacy.⁹⁰⁴ These were stated as reasons for a simplified procedure called ‘traditional-use registration’, which was created by Directive 2004/24/EC for traditional herbal medicinal products. The Member States have had to apply the new legislation since 2005. To maintain these products on the market, the Member States had enacted various requirements and procedures. Harmonised rules were considered appropriate, as the differing member state rules distorted competition and did not always adequately address the safety and efficacy issues.⁹⁰⁵

The simplified procedure is applicable to products which fulfil *all* of the following criteria⁹⁰⁶:

- “(a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for *use without the supervision of a medical practitioner* for diagnostic purposes or for prescription or monitoring of treatment;
- (b) they are exclusively for administration in accordance with a specified strength and posology;
- (c) they are an oral, external and/or inhalation preparation;
- (d) *the period of traditional use* as laid down in Article 16c(1)(c) has elapsed;
- (e) the data on the traditional use of the medicinal product are sufficient; in particular *the product proves not to be harmful in the specified conditions of use* and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience”.

The period of traditional use is decisive here. *The period is 30 years, of which at least 15 are within the community area.* The Alliance for Natural Health, along with other organisations, campaigned to accept 30 years demonstrated safe use *anywhere in the world*. They claimed that limiting non-EU use would prevent interesting and beneficial herbs discovered in parts of the world with very strong herbal cultures (e.g. China, India, South East Asia, South Africa, South America) from being brought to Europe. They argued that the legislation would strongly impact future innovation, and have the effect of freeze-framing the industry in the early 1990s.⁹⁰⁷ The Commission and the Parliament did not accept these arguments.

In the traditional-use registration, the applicant must provide the authorities with bibliographical or expert evidence to prove that the medicinal product in question, or a corresponding product, has been in medicinal use for at least 30 years preceding the date of the application, including at least 15 years within the Community. He must also deliver a bibliographic review of safety data together with an expert report. The authorities may also request additional data that is considered necessary for assessing the safety of the medicinal product.⁹⁰⁸ According to Article 16 f of the Medicinal Products Directive, a Community list

⁹⁰⁴ Silano et al. 2004, 108.

⁹⁰⁵ Preamble 3 of Directive 2004/24/EC.

⁹⁰⁶ Medicinal products directive, Article 16a(1).

⁹⁰⁷ Wogan’s Silent Betrayal web page at <http://www.silentbetrayal.com/vitamins.htm>.

⁹⁰⁸ Directive 2001/83/EC, Article 16c(1)(c) and (d).

of traditional herbal medicines is created. If the medicinal product is on this list, the applicant does not need to deliver the above-mentioned bibliographical and expert reports.

The herbal medicinal product may also contain *vitamins or minerals* for the safety of which there is well-documented evidence. The action of vitamins or minerals must support be ancillary to the effect of the herbal active ingredients regarding the specified claimed indication.⁹⁰⁹ This reflects the fact that most of the traditional combination products between herbal and non-herbal ingredients are indeed combinations with vitamins and minerals⁹¹⁰.

If the authorities judge that a traditional herbal medicinal product fulfils the criteria for authorisation of normal medicinal products (Article 6 of the medicinal products directive) or registration as a homeopathic medicinal product (Article 14 of the medicinal products directive), the traditional herbal medicine alternative does not apply.⁹¹¹ If there is sufficient scientific literature to prove established medicinal use, recognised efficacy and an acceptable safety level, the applicant should apply for marketing authorisation for the product⁹¹².

The amendment concerning traditional herbal medicinal products clarifies the previous situation, where the distinction between medicinal and non-medicinal use of some herbs was blurred⁹¹³. Some food-form products with health effects now go under the definition of traditional herbal medicinal products. However, the scientific grounds for creating the category sound weak. The category was created because there is not enough evidence on some herbs, but still these products are considered safe and effective enough to be sold to consumers. The *scientific difference between “well-established use” and “traditional use”* remains unclear. *Third country use applies for neither.*

4.3.1.4 Homeopathic Medicinal Products

Homeopathic medicinal products are defined in Article 1.5 of the medicinal products directive 2001/83/EC:

“Homeopathic medicinal product: Any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may also contain a number of principles⁹¹⁴.”

Homeopathy is an alternative medicine attempting to treat “like with like”. In homeopathy, the sick are treated with extremely diluted agents that, in undiluted doses, produce similar symptoms in the healthy. It is asserted that the therapeutic potency of a remedy can be increased

⁹⁰⁹ Medicinal products directive, Article 16a(2).

⁹¹⁰ Silano et al. 2004, 110.

⁹¹¹ Medicinal products directive, Article 16a(3).

⁹¹² National Agency for Medicines web page: http://www.nam.fi/english/pharma_industry/herbal_remedy/traditional_herbal/index.html.

⁹¹³ Silano et al. 2004, 108.

⁹¹⁴ According to freedictionary.com, principle means “a constituent of a substance, especially one giving to it some distinctive quality or effect”. This means that a homeopathic product can contain several acting agents.

by serial dilution of the drug, combined with mixing and shaking techniques. Homeopathy is inconsistent with laws of chemistry and physics.⁹¹⁵ Better-quality clinical trials on the effects of homeopathy are more likely to give negative results.⁹¹⁶

Homeopathic medicines can be authorised in the primary procedure for medicines or registered through a simplified procedure. According to preamble 21 of the medicinal products directive, particular characteristics of homeopathic medicinal products create a need for a simplified procedure for certain homeopathic products. These characteristics are “*the very low level of active principles ... and the difficulty of applying ... conventional statistical methods relating to clinical trials*”.

The special provisions concerning the simplified procedure applicable to homeopathic medicinal products are in chapter 2 of the medicinal products directive. Article 14 lists the conditions for the simplified procedure:

“Only homeopathic medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

- they are administered orally or externally,
- *no specific therapeutic indication* appears on the labelling of the medicinal product or in any information relating thereto,
- there is *a sufficient degree of dilution* to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor’s prescription.”

From a safety point of view, dilution is the key. Homeopathic products are very weak. The safety requirements for homeopathic medicinal products are the same regardless of whether or not an indication is suggested. According to Finnish agency of medicines⁹¹⁷, either the safety must be demonstrated through original studies, or it must be shown on the basis of published literature that the dilution concerned is safe in relation to the method of administration in question. An expert statement on the safety of the product should also be presented.

As explained above, believers of homeopathy consider that the effective ingredient is effective even when highly diluted. From the efficacy point of view, a very critical notion is to be found in article 14.3: *No proof of therapeutic efficacy is required* of the homeopathic products registered according to the simplified procedure. Article 15 lists the information needed in the simplified procedure: *bibliographical data* concerning the product’s homeopathic nature, data

⁹¹⁵ Wikipedia. <http://en.wikipedia.org/wiki/Homeopathy>.

⁹¹⁶ Shang et al. 2005.

⁹¹⁷ National Agency for Medicines web page. http://www.nam.fi/english/pharma_industry/herbal_remedy/homeopathic/index.html.

on the stability of the product etc.⁹¹⁸. According to preamble 23 of the Medicinal Products Directive, “it is desirable in the first instance to provide users of these homeopathic medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety”. “Guarantees of efficacy” was left out on purpose.

Homeopathic medicinal products, *other than those qualified for the simple procedure* shall be authorised and labelled in accordance with Articles 8, 10 and 11, i.e. like normal medicines. These are products with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect⁹¹⁹.

A Member State may refrain from establishing a special, simplified registration procedure for the homeopathic medicinal products. This means a compromise: countries that do not value homeopathy can keep the products off the market. Countries that trust homeopathy, can allow them to exist via the simplified procedure. The practitioners of homeopathy and other complementary and alternative medicines (CAM) claim that the situation where Member States can make up their own minds creates several problems. Of course they wish their treatments would be recognised everywhere. European countries vary greatly regarding regulation of CAM products and practitioners. In some countries, practitioners can operate freely and products are available to patients. Health insurance providers even reimburse some CAM products. Authorities and doctors in the new Member States are apparently reluctant to accept CAM products.⁹²⁰

The consumer can choose to trust or not to trust homeopathy. The homeopathy business sees the European harmonisation of the legislation on homeopathic medicine in 1992⁹²¹ as a turning point constituting “official recognition of homeopathic medicine in all EU countries”. The supporters claim that, “*this Community recognition demonstrates homeopathic medicine’s integration into the European medical and pharmaceutical world*”.⁹²² The scientific grounds for creating the simplified procedure for homeopathic

⁹¹⁸ Article 15: “An application for special, simplified registration may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned:

- scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered,
- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography,
- manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation,
- manufacturing authorisation for the medicinal product concerned,
- copies of any registrations or authorisations obtained for the same medicinal product in other Member States,
- one or more specimens or mock-ups of the outer packaging and the immediate packaging of the medicinal products to be registered,
- data concerning the stability of the medicinal product.”

⁹¹⁹ Preamble 25 of the medicinal products directive.

⁹²⁰ The European Council for Classical Homeopathy. 31 January 2007. A response to: Communication from the Commission. Consultation regarding Community action on health services, Brussels, 26 September 2006.

⁹²¹ With the adoption of two directives concerning homeopathic medicine for human and veterinary use.

⁹²² Boiron Group homeopathy site at: <http://www.boiron.com/en/htm/homeopathy-today/homeopathy-regulation.htm>.

medicines are questionable. The “*difficulty of applying conventional statistical methods relating to clinical trials*” is used as a ground for special legislation, but the legislator does not explain this difficulty.

4.3.2 China

In China, there are essentially two different kinds of medicinal products on the market: modern medicines and traditional Chinese medicines. With regard to modern medicines, there are specific standards for narcotics, psychotropic substances, toxic drugs for medicinal use, and radioactive medicines⁹²³. These will not be discussed here.

4.3.2.1 Modern Medicines

In the past few years, China has significantly modernised its legislation on medicines, in order to guarantee their safety, efficacy, and quality. China has simultaneously enhanced intellectual property protection, which is particularly important to the medicine industry.⁹²⁴

The central government authority responsible for medicine control is the State Food and Drug Administration. A new medicine can be put into production only after the SFDA has approved it and issued a registered document of approval⁹²⁵. A new medicine which has completed its clinical tests and been approved after appraisal shall be issued a certificate of new medicine by the SFDA⁹²⁶.

First, production and sale of fake medicines is prohibited. A fake medicine has any one of the following characteristics:

- (1) Its components do not comply with State pharmaceutical standards.
- (2) A non-medical substance is passed off as a medicine, or one medicine is passed off as another.⁹²⁷

A medicine is legally a fake medicine in any of the following cases:

- (1) Where the use of the medicine has been prohibited by the SFDA;
- (2) Where the medicine is produced and imported without a legal approval or sold without being inspected according to the law;
- (3) Where the medicine has deteriorated;
- (4) Where the medicine has been contaminated;
- (5) Where the medicine has been produced of medicinal materials without obtaining a registration document of approval for the materials.

⁹²³ Based on Medicine Administration Law, Article 35.

⁹²⁴ Tsoi 2007.

⁹²⁵ Medicine Administration Law, Article 31.

⁹²⁶ Medicine Administration Law, Article 29.

⁹²⁷ Medicine Administration Law, Article 48.

- (6) Where the indications or the functions marked on the label do not fall within the prescribed scope.⁹²⁸

Second, production and sale of medicines of inferior quality is prohibited. This refers to medicines whose components do not conform to State pharmaceutical standards⁹²⁹. These standards are the “Pharmacopoeia of the People’s Republic of China” and the pharmaceutical standards promulgated by the SFDA.⁹³⁰ A medicine shall be handled as medicine of inferior quality also in any of the following cases:

- (1) An expiry date is not indicated or is altered; or
- (2) A registration number is not indicated or is altered; or
- (3) The medicine has passed its expiration date; or
- (4) The packages and containers which have direct contact with pharmaceuticals have not obtained approval; or
- (5) The medicine has been added to presumptuously with colour or preservative additives, spice, disguising odour or supplementary materials; or
- (6) The medicine fails to meet the prescribed standards in other respects⁹³¹.

Import of medicines whose curative effects are uncertain or poor, or which produce adverse reactions or have other harmful effects on people’s health is prohibited⁹³².

4.3.2.2. *Traditional Chinese Medicines*

4.3.2.2.1 What is Traditional Chinese Medicine

Traditional Chinese Medicine means a medical science governing the theory and practice of traditional Chinese medicine. It is an ancient Chinese system of medicine that includes meditation, herbal and nutritional therapy, restorative physical exercises and massage, and acupuncture⁹³³. Here we are mainly interested in herbal medicines. Herbal medicines and plant-based functional foods have important features in common, but the differences of the legal categories affect strategy on product development and marketing.

According to a recent survey, the number of traditional Chinese medicines is close to 13000. Of these, over 11000 are of plant origin; the rest are of animal or mineral origin. This means traditional Chinese medicine often refers to herbal medicine.⁹³⁴

Since the 1920s, traditional Chinese medicines have been investigated in terms of modern medical science. Chemical ingredients and fractions have been isolated from herbs, and their actions studied. Since the 1950s, the Chinese government has paid a lot of attention to the development of traditional Chinese medicine. Colleges focused on the subject have

⁹²⁸ Medicine Administration Law, Article 48.

⁹²⁹ Medicine Administration Law, Article 49.

⁹³⁰ Medicine Administration Law, Article 32.

⁹³¹ Medicine Administration Law, Article 49.

⁹³² Medicine Administration Law, Article 38.

⁹³³ Spondylitis Association of America. Web page at: http://www.spondylitis.org/patient_resources/glossary.aspx.

⁹³⁴ The Essentials of Traditional Chinese Herbal Medicine 2003, 1.

been established in every province and autonomous region; hospitals and research institutes have been set up at national, provincial, municipal and even county level. New chemical ingredients are isolated. New forms of herbal remedies are instant powders, tablets, injections and capsules.⁹³⁵

Medicines of plant origin form the main part of traditional Chinese medicine. Their species, habitat, collection season, collection method, and storage are thus important factors determining their quality and efficacy. For example, some plants need to be collected when flowers are in full bloom, others when flowers are still in bud. Medicines from fruits are usually collected when the fruits are ripe, medicines from roots in late autumn or spring, and medicines from bark in early summer.⁹³⁶

Herbal medicines are processed before being taken as medicines. Sometimes the purpose of processing is increasing potency, and hence effectiveness. Sometimes it is minimising or eliminating side effects or toxicity. Sometimes processing makes drugs easier to prepare or store. Methods of processing can be divided into physical processing, liquid processing, fire processing and processing by both water and fire. Side effects are often reduced by boiling or steaming.⁹³⁷

Diseases are classified into two major categories: cold and hot. Medicines to counteract these diseases are cool, cold, warm or hot. In terms of yin and yang, cool and cold belong to yin, and warm and hot belong to yang. Hot diseases are ones where body temperature, blood pressure, respiratory rate, and saliva secretion are high. Cold diseases are the opposite. Hot diseases are treated with cold medicines and the other way around. Hot or warm drugs stimulate the central nervous system; promote the metabolic system and so on. Cold and cool drugs tranquilise, sedate, and have anti-microbial and anti-inflammatory actions.⁹³⁸ The taste of a drug is related to its therapeutic capability.⁹³⁹

In terms of safety or toxicity, traditional Chinese medicines can be classified as non-toxic, slightly toxic, moderately toxic and extremely toxic. Even some extremely toxic herbs thus have their medical uses. According to ancient literature, it is stated that *no drug is non-toxic* if taken in excessive doses or for too long a period of time. When using traditional Chinese medicines, the properties, actions and toxicity are weighed against one another. Medicines are chosen according to the syndrome, and the doctor must look at the situation as a whole.⁹⁴⁰ Dosage and method and time of administration are determined simultaneously⁹⁴¹. For mild diseases and for children and other weak persons, dosage is smaller⁹⁴².

This approach is similar to Western medicine where it is acknowledged that all medicines have side effects, a risk-benefit ratio is applied, and appropriate dosage is an integral part of treatment. The biggest difference is that *in traditional Chinese medicine, a large part of the information is based on long history of use*, not exact clinical trials.

When discussing medicine safety, interactions of substances have to be taken into account. This includes medicine-medicine interactions and medicine-food interactions.

⁹³⁵ The Essentials of Traditional Chinese Herbal Medicine 2003, 2.

⁹³⁶ The Essentials of Traditional Chinese Herbal Medicine 2003, 3.

⁹³⁷ The Essentials of Traditional Chinese Herbal Medicine 2003, 4-5.

⁹³⁸ The Essentials of Traditional Chinese Herbal Medicine 2003, 5-6.

⁹³⁹ The Essentials of Traditional Chinese Herbal Medicine 2003, 6.

⁹⁴⁰ The Essentials of Traditional Chinese Herbal Medicine 2003, 8.

⁹⁴¹ The Essentials of Traditional Chinese Herbal Medicine 2003, 10-11.

⁹⁴² The Essentials of Traditional Chinese Herbal Medicine 2003, 10.

In clinical practice, traditional Chinese medical doctors usually prescribe around ten or more herbs to make the best possible mixture in each individual case of symptoms. The medicines in a mixture can be classified into four categories:

- the principal medicine(s) provides the principal curative action,
- the adjuvant medicine(s) strengthens this action and treats secondary symptoms,
- the auxiliary or corrective medicine(s) relieves secondary symptoms or tempers the action of the principal medicine,
- the conductive medicine(s) directs the action to the right part in the body.⁹⁴³

Medicines in a prescription can either reinforce each other, weaken each other, neutralise side effects of each other, counteract each other (resulting in no therapeutic action), or are totally incompatible, where two drugs put together will result in enhanced side effects or toxicity.⁹⁴⁴

There are lists of counteracting and incompatible medicines available to doctors. There are eighteen incompatible medicaments and nineteen medicaments of mutual restraint. For example, if Radix Veratri Nigri (lilu) is put together with Radix Ginseng, there will be serious side effects. If Radix Ginseng is put together with Faeces Troglodyterum (wulingzhi), Ginseng neutralizes the effect of Troglodyterum. The mechanisms of these actions are not clear.⁹⁴⁵ As there are 11000 medicinal herbs in use, and relatively few are cited in the above-mentioned incompatibility list, it is evident that a lot more research is needed on herbal interactions.

There is also a list of herbs that should not be used *during pregnancy*, as they might harm the foetus or cause abortion. Drugs that are prohibited or should be used with caution during pregnancy are those that have a drastic action or are very toxic. These are for example Flos Genkwa and Radix Euphorbiae Pekinensis. Also, drugs that are very warm or purgative should be avoided.⁹⁴⁶

There are also guidelines on unwanted *medicine-food interactions*. Uncooked or cold food is not suitable for a person suffering a cold syndrome. Hot and greasy food is not suitable for persons with a hot syndrome: for example, insomniacs should not ingest chillies. Some medicaments do not work well together with for example Chinese green onion, garlic and radish. Peppermint counteracts turtle flesh, honey counteracts scallions, and so on.⁹⁴⁷

4.3.2.2.2 The Law on Traditional Chinese Medicine

According to the Chinese Medicine Administration Law⁹⁴⁸, “the State shall develop *both modern and traditional medicines* and encourage their role in the prevention and treatment of diseases and in health care”. Further, “the State shall protect the resources of wild medicinal resources

⁹⁴³ The Essentials of Traditional Chinese Herbal Medicine 2003, 8-9.

⁹⁴⁴ The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

⁹⁴⁵ The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

⁹⁴⁶ The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

⁹⁴⁷ The Essentials of Traditional Chinese Herbal Medicine 2003, 9.

⁹⁴⁸ The Medicine Administration Law of the People’s Republic of China, revised at the Twentieth Meeting of the Standing Committee of the Ninth National People’s Congress on February 28, 2000. The revised law entered into force as of December 1, 2001.

and encourage the domestic cultivation of Chinese traditional medicinal crops".⁹⁴⁹ Traditional medicine is clearly given more weight compared to the European law on medicines.

The national Regulations on Traditional Chinese Medicine have been effective as of October 2003⁹⁵⁰. These Regulations do not specify rules on safety, efficacy and marketing of traditional medicines. Instead, the Regulations are focused more on attitudes towards and roles of traditional medicine. The objectives of the Regulations include:

- the development of the science of traditional Chinese medicine,
- the promotion of the development of undertakings engaged in traditional Chinese medicine, and
- the protection of public health.⁹⁵¹

The Regulations apply to institutions and individuals engaged in healthcare involving traditional Chinese medicines, as well as to education, research and international cooperation related to the subject. The objectives of the State are to protect, support, and develop traditional Chinese medicine. The aim is to place equal stress on traditional Chinese medicine and Western medicine and encourage development and integration of both schools.⁹⁵²

The Regulations on Traditional Chinese Medicine do not include criteria on product safety, efficacy and marketing. Product development, production, marketing, use, supervision, and administration with respect to traditional Chinese medicines must comply with the Medicine Administration Law of the People's Republic of China. It is stated in Article 6, that the preparation of Chinese medicines shall be in accordance with the "Pharmacopoeia of the People's Republic of China", or in accordance with the "Preparation Standards" laid down by the department administering health in that province, autonomous region or municipality under the direct control of the Central Government.

Many of the safety problems with traditional Chinese medicines are due to poor quality. This means the plant itself might be safe, but due to heavy metal contamination or adulteration with prescription drugs, the product is dangerous. There may also be quantitative variations in constituents, which affect safe use of the product.⁹⁵³ Quality issues are not discussed here, as we are more interested in the safety of the therapeutic ingredient itself.

As stated above, the law does not specify criteria on traditional medicines yet. The safety of traditional medicines is guaranteed by the traditional guidelines described in the previous chapter. At the beginning of 2007, the Chinese Ministry of Health completed the drafting of Law on Traditional Chinese Medicine, which was submitted to the State Council. The

⁹⁴⁹ Article 3.

⁹⁵⁰ Regulations of the People's Republic of China on traditional Chinese medicine. Adopted at the Third Executive Meeting of the State Council on 2 April 2003. Promulgated by Decree No. 374 of the State Council of the People's Republic of China on 7 April 2003. (Gazette of the State Council of the People's Republic of China, 30 May 2003, Issue No. 15, Serial No. 1086.)

⁹⁵¹ Summary of the Chinese Regulations on Traditional Chinese Medicines by the WHO's "international digest of health legislation". Available on the WHO web page at: <http://www.who.int/idhl-rils/frame.cfm?language=english>.

⁹⁵² Summary of the Chinese Regulations on Traditional Chinese Medicines by the WHO's "international digest of health legislation". Available on the WHO web page at: <http://www.who.int/idhl-rils/frame.cfm?language=english>.

⁹⁵³ Barnes 2003.

drafting of the law had drawn considerable attention from the National People's Congress (NPC) and government departments.⁹⁵⁴ The goal of the Chinese government is to strengthen supervision on the sources of Chinese medicines, improve the administrative system for Good Chinese Medicine Production Practice (GCMP), push forward the implementation of GCMP and ensure the production quality of Chinese herbal medicines.⁹⁵⁵

Improving the legal framework on traditional medicine is among the important goals set by the Chinese government for the forthcoming years. The goal is to establish and improve a system of Chinese traditional medicine standards. A comprehensive classification system of Chinese medicine is needed. Technical pre-market evaluation criteria shall be set, followed with post-market control criteria. To strengthen the knowledge base, research-guiding principles of reference materials will be formulated, and a Chinese medicine library for standard materials will be established. China will actively advocate the establishment of international standards for traditional medicines.⁹⁵⁶

In China, Traditional Chinese Medicine is under the administration of State Administration of Traditional Chinese Medicine and Pharmacology, which is under the Ministry of Health. National strategies, laws and regulations governing Traditional Chinese Medicine are in place to guide and promote the research and development in the industry.⁹⁵⁷ Also the Ministry of Science and Technology has initiated a programme that has ambitious goals related to Traditional Chinese Medicine. They have a programme called "International Traditional Chinese Medicine Programme for Cooperation in Science and Technology". The aim is to facilitate integration of traditional medicine with Western medicine all over the world.

4.4 Conclusions on Food and Medicine Safety in EU and China

In law, there are no particular safety requirements for functional foods. This is because in law, there are no 'functional foods'. The legal safety criteria for functional foods are those that are stipulated for microbes, additives, contaminants and residues, fortification, novel foods, and GMOs, or, they are the safety criteria stipulated for (herbal) medicines. The safety criteria set for foodstuffs vs. medicines differ considerably, the main difference being that medicines have *side effects*.

The general aim of food safety legislation is the same in EU and China: protecting consumers from unhealthy products, encompassing biological and chemical hazards. Both in Europe and China, there are several regulatory categories with specific safety rules on different types of food products. These categories relate to different types of technological or chemical risks. In China, additives, health foods, novel foods, and GM foods are regulated separately. All have their separate pre-market authorisation procedures. In Europe, separate legislation exists on additives, food supplements, food fortification, dietetic foods, novel foods, and GMO foods.

The Chinese health food category covers a wide range of products and includes the European categories of food supplements, fortified foods, and dietetic foods. *Functional foods*

⁹⁵⁴ People's Daily Online. January 17 2007. Available at: http://english.people.com.cn/200701/14/eng20070114_341062.html

⁹⁵⁵ Five-Year Plan for Food and Drug Safety. April 2007. Page 12.

⁹⁵⁶ Five-Year Plan for Food and Drug Safety. April 2007. Pages 12-13.

⁹⁵⁷ Chinese Symbols web page. <http://www.chinese-symbols.com/chinese-medicine/chinese-medicine.html>.

will often fit to the Chinese category of health foods. The category of novel foods is more restricted in China than in Europe, and functional foods will likely not be categorised as novel foods in China.

In Europe, there is no single category for health foods or functional foods. Functional foods might legally be classified as ‘normal foods’ or dietetic foods. This is basically a marketing question and will be discussed below. *European fortification rules and novel food regulations are often relevant to functional foods* if products contain something additional or new as compared to common, basic, old-fashioned food products.

The rules on medicine safety are also largely the same in EU and China. Compared to food safety, medicine safety is more relative to the efficacy of the product, whereas food safety is more of an absolute requirement. The risk/benefit ratio is applied to medicines. All effective medicines have some side effects and should only be used if needed.⁹⁵⁸ Medicine safety is guaranteed by strict procedures on tests and trials, scientific risk assessment, pharmacovigilance, and by comprehensive user information. With herbal medicines, safety assessment is affected by nature: the plants vary as to where they grow.

In Europe, food that is familiar is presumed safe. Both the European novel food regulation and the European legislation on herbal medicines are more sympathetic to European products. This has been a constant cause for disputes in the international arena. In China, there have been serious incidents both with unsafe foods and unsafe medicines. China has the dual task of convincing both their own citizens and other countries of the safety of Chinese foodstuffs and medicines.

⁹⁵⁸ Kwak – Jukes 2000a, 105.



5 **MARKETING OF FOODSTUFFS AND MEDICINES**

5.1 **General Marketing Rules**

5.1.1 **EU**

Regulating advertising is one of the basic elements of consumer protection law. In the EU, the Misleading Advertising Directive from 1984⁹⁵⁹ provided minimum standards to ban misleading advertising. The directive was updated in 1997 to allow comparative advertising under certain conditions. That Directive stipulated that Member States shall ensure that adequate and effective means exist to combat misleading advertising⁹⁶⁰. As the Directive did not give any specific rules, national differences remained.

The UCP directive of 2005⁹⁶¹ introduced a general duty on all businesses not to trade unfairly with consumers. Member States should have implemented the directive by December 2007. The directive is applicable to all *business-to-consumer commercial practices*. The concept of ‘commercial practice’ is not limited to advertising. It encompasses “any act, omission, course of conduct or representation, commercial communication including advertising and marketing”⁹⁶². The directive applies to unfair business-to-consumer commercial practices “during and after a commercial transaction in relation to a product”⁹⁶³.

The *general clause* contains the general ban on unfair commercial practices. Two defining criteria are used to identify an unfair commercial practice - a commercial practice is regarded as unfair if it meets the following two, cumulative criteria:

⁹⁵⁹ Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising.

⁹⁶⁰ For the purposes of the directive, ‘advertising’ means “the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations”. ‘Misleading advertising’ means “any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reasons of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor”. Article 4(1).

⁹⁶¹ The UCP Directive, directive on unfair commercial practices 2005/29/EC of 11 May 2005.

⁹⁶² Article 2(d).

⁹⁶³ Article 3.1.

1. The practice is contrary to the requirement of *professional diligence*. Professional diligence is “the special skill and care which a trader may reasonably be expected to exercise, commensurate with honest market practices and/or general principle of good faith in the trader’s field of activity.”
2. The practice *materially distorts or is likely to materially distort the average consumer’s economic behaviour*. The criterion “to materially distort the economic behaviour of consumers” means using a commercial practice to appreciably impair the consumer’s ability to make an informed decision, thereby causing the consumer to take a transactional decision that he would not have otherwise taken.

Two main categories of unfair commercial practices - “misleading” and “aggressive” practices - are described in more detail. A commercial practice is *misleading* if it either:

- Contains false information and is therefore untruthful, *or*
- In any way, including overall presentation, deceives or is likely to deceive the *average consumer*, even if the information is correct *and*
- Causes or is likely to cause him to take a transactional decision that he would not have otherwise taken.

Omissions might also be considered misleading. It is misleading to:

- Omit material information that the *average consumer* needs, according to the context, to take an informed transactional decision;
- Hide or provide material information in an unclear, unintelligible, ambiguous or untimely manner;
- Fail to identify the commercial intent of the commercial practice if not already apparent from the context.

Regulating *aggressive* commercial practices is new at the EU level. A practice is considered aggressive if the average consumer’s freedom of choice or conduct is significantly impaired. The Directive contains a list of criteria to help determine whether a commercial practice uses harassment, coercion, including physical force, or undue influence. “Undue influence” means “exploiting a position of power in relation to the consumer so as to apply pressure, even without using or threatening to use physical force, in a way which significantly limits the consumer’s ability to make an informed decision.”

Finally, the Black List contains the list of those practices, which shall, in all circumstances, be regarded as unfair and thus banned – without applying the average consumer test⁹⁶⁴.

⁹⁶⁴ The black list includes, without going into details of each marketing method:

- Trust marks and codes
- Bait advertising
- Bait and switch
- Limited offers: Special offer, today only!
- Language of after-sales service: Marketing in English, after-sales services in Swedish
- Advertising products which cannot be legally sold
- Misleading impression of consumers’ rights: “Special for you”

The Directive provides for special protection to vulnerable consumers. When a commercial practice is targeted at a specific group of consumers, the impact of the practice will be assessed from the perspective of the average member of the group in question. For example, in the case of advertising to children, the *average child* of the relevant age group will be the benchmark. Certain commercial practices are prohibited since they typically affect vulnerable consumers in that case. Examples of such practices include:

- a) claiming that products are able to facilitate winning in games of chance,
- b) falsely claiming that a product is able to cure illnesses, dysfunction or malformation, or
- c) including in an advertisement a direct exhortation to children to buy advertised products or persuade their parents or other adults to buy advertised products to them.

Some of the UCP protections replicate previous legislation of various Member States, but others are new.⁹⁶⁵ The Misleading Advertising Directive did not contain any Black List of practices that are banned under all circumstances, and there was no common standard for protecting vulnerable consumers. According to the Commission, the new legislation “harmonises EU rules on business-to-consumer commercial practices, with the aim of clarifying consumers’ rights and boosting cross-border trading”⁹⁶⁶.

Advertorials: “Mixed messages”

Security as marketing argument: Unduly playing on fear of security risks

Decoy: “Reputable brand, or maybe not?”

Pyramid schemes

False claims regarding moving premises or cessation of business: “End of lease! All stock must go!”

Facilitation of winning chances: How to win the lottery

False claims about curative capacity: “Trickium 24 cures disease”

Market information

Prizes: “Congratulations! You have won a prize”

Falsely creating the impression of free offers: “Free sunglasses”

Products not ordered

Professional trader disguised as consumer

After sales services: “Europe-wide guarantees”

Pressure selling: “Yes, you can leave once the paperwork is done”

Aggressive doorstep selling: “Yes, I will leave, once the paperwork is done”

Persistent and unwanted solicitations: “With the third phone call maybe a contract will be agreed...”

Insurance claims: No one picks up the phone

Direct exhortations to children: “Go buy the book!”

Inertia Selling

Emotional pressure

Prize Winning.

⁹⁶⁵ The UK Department of Trade and Industry. The Unfair Commercial Practices (UCP) Directive. Executive Summary of the Consultation on implementing the EU directive on Unfair Commercial Practices and Amending Existing Consumer Legislation. December 2005.

⁹⁶⁶ European Commission web page. http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=37.

The directive uses maximum harmonisation, which means that Member States may not impose more restrictive national legislation. Dickie critiques the Commission's push for maximum harmonisation in consumer protection. According to Dickie, the idea of high common *maximum* level of consumer protection, presented as an objective in the Commission's Consumer Protection Strategy 2002-2006⁹⁶⁷, is novel and without grounds⁹⁶⁸. The Consumer Protection Strategy 2007-2013 clearly states that minimum harmonisation might have been suitable in the past but "full harmonisation" is the Commission's current approach⁹⁶⁹.

Howells et al. also critique the maximum harmonisation approach in consumer protection. They point out that European *consumers have different expectations* concerning *consumer law*. There is empirical evidence suggesting that 80% of Finns trust regulators to guarantee consumer rights, as opposed to 20% of Greek consumers. This difference in expectations concerning legal protection means a difference in expectations concerning how cautiously one must behave when acting on the consumer market. It is difficult to adapt European legislation based on maximum harmonisation to such variations, without leading to considerable losses to consumers left with 'false' expectations.⁹⁷⁰

It has to be noted that the UCP Directive protects the *economic interest* of the consumer, and only indirectly other interests such as health or safety. In addition, taste and decency are outside the scope of application of the Directive.⁹⁷¹ Health and safety are regulated separately by general product safety and sector-specific product safety requirements, discussed in chapter 4 above.⁹⁷² The right to safe and healthy products and the right to adequate information are not actually far from each other. As opposed to physical safety, *marketing rules could be seen as guaranteeing economic safety of consumers*.

The UCP directive only applies in business-to-consumer relationships. If interpreted literally, this means that competitor companies may not base claims on the directive. UK marketers have proposed an interpretation according to which competitor businesses are still entitled to retain rights of action under the directive, as *companies are harmed if their consumers are deceived*⁹⁷³. It is stated in the Directive that it "*indirectly* protects legitimate businesses from their competitors who do not play by the rules"⁹⁷⁴. This means the directive is not *directly* meant to protect competitors. However, the right of action is not exactly limited to consumers, either. It is also acknowledged that there are commercial practices which, although not harming consumers, may hurt competitors and business customers, and that Commission should consider further legislation addressing these issues⁹⁷⁵. In the future, competitor companies may base their demands on business-to-business legislation, without having to grasp on indirect protection through their consumers.

⁹⁶⁷ EU Consumer policy strategy 2002-2006.

⁹⁶⁸ Dickie 2003.

⁹⁶⁹ EU Consumer policy strategy 2007-2013, 16.

⁹⁷⁰ Howells et al. 2006, 258.

⁹⁷¹ The Unfair Commercial Practices Directive. An information leaflet on European Commission web page at http://ec.europa.eu/consumers/cons_int/safe_shop/fair_bus_pract/ucp_en.pdf.

⁹⁷² The Unfair Commercial Practices Directive. An information leaflet on European Commission web page at http://ec.europa.eu/consumers/cons_int/safe_shop/fair_bus_pract/ucp_en.pdf.

⁹⁷³ British Brands Group 2007. The British Brands Group is particularly worried about copycat packaging and inadequate means to tackle it.

⁹⁷⁴ Preamble 8.

⁹⁷⁵ Preamble 8.

Marketers continue to come up with new, innovative practices, which might be considered unfair. The UCP directive with its general clause may be used as a tool to contribute to uniform application of existing and future EU information, advertising, and labelling requirements. *Where Lex specialis*⁹⁷⁶ exists, it takes precedence over the UCP directive. However, the UCP directive potentially improves enforcement of Lex specialis rules, because it provides national consumer protection authorities with an *additional legal basis* to enforce the information requirements. An omission to provide material information which the average consumer needs can be misleading under UCP. Therefore, UCP may also be used as a tool to *fill in gaps* in labelling and advertising legislation.⁹⁷⁷ This applies for example to marketing of foodstuffs and medicines.

However, interpretation of UCP through case law is slow. The UCP Directive foresees no committee where unclear issues could be settled. The Commission might therefore develop some kind of informal “guidance” system to alert business and enforcement authorities of Commission’s interpretation of unfair commercial practices. Member States could not be legally obliged to comply with Commission interpretations. According to the Commission, the guidance approach has proved helpful to economic operators in similar cases where new law risked creating uncertainty.⁹⁷⁸

The impossibility to include all the scientific and technical details in legislation together with the impossibility of leaving all the interpretation to courts here seems to lead to the guidance approach. The guidance approach leads to soft law, which is often welcomed by regulation targets but the binding nature of which is legally unclear. If we give a general directive like the UCP directive, we have to carefully consider who we want to interpret it and fill in the gaps. Making binding interpretation can be left either to courts or to a specific Committee. In addition, non-binding instruments can be used.

5.1.2 China

The general rules on marketing are in China given by the Advertisement law⁹⁷⁹. The law is formulated to “regulate advertising activities, to promote the sound development of the advertising sector, to protect the lawful rights and interests of consumers, to maintain the social and economic order, and to let advertisements play an active role in socialist market economy”⁹⁸⁰. It concerns Advertisers, advertising agents and advertisement publishers acting within the territory of the People’s Republic of China. Advertisement is defined as “any commercial advertisement, which a supplier of goods or services pays for, to introduce their goods or services whether directly or indirectly through the media in all its forms to Public at large”⁹⁸¹.

⁹⁷⁶ Here *Lex specialis* means sector-specific rules on marketing.

⁹⁷⁷ Labelling: competitiveness, consumer information and better regulation for the EU. A DG SANCO Consultative Document February 2006, 4.

⁹⁷⁸ Labelling: competitiveness, consumer information and better

regulation for the EU. A DG SANCO Consultative Document February 2006, 4.

⁹⁷⁹ Advertisement Law of the People’s Republic of China. Adopted at the 11th Meeting of the Standing Committee of the Eighth National People’s Congress on October 27, 1994, promulgated by Order No.34 of the President of the People’s Republic of China on October 27, 1994, and effective as of February 1, 1995.

⁹⁸⁰ Article 1.

⁹⁸¹ Article 2.

The Chinese law is more specific than the European directive. The most general rules of advertising are given in Articles 3 to 5: Advertisements must be factual and lawful, and comply with the principles of advancing socialist culture and ideology⁹⁸². An advertisement must not contain any information, which is *false and or misleading* so as to deceive the consumers⁹⁸³. Advertisers, advertising agents and publishers engaged in advertising activities shall act according to law and administrative regulations in a *spirit of fairness and integrity*⁹⁸⁴.

The specific rules on the contents of advertisements are given in Chapter 2 of the Law. According to Article 7, the contents of advertisements shall:

- lead towards the physical and mental health of the people,
- promote the improvement in quality of goods and services,
- protect the lawful rights and interests of consumers,
- comply with social morality and professional ethics, and
- safeguard the dignity and interests of the state.

It is noteworthy that promoting health is first mentioned among advertising tasks. Article 8 mentions health again: “Advertisements may not impair the physical and mental health of minors and the disabled”. Foodstuffs and medicines are both widely used and widely advertised consumer products having direct effects on health. Therefore, it is safe to say that regulating food and medicine advertising is one of the key tasks of consumer protection law, and perhaps the most important task of advertising law.

According to Article 9, statements in advertisements of the performance, origin of production, use, quality, producer, etc. of the goods advertised shall be *clear and explicit*. References to scientific information are covered by Article 10: Data, statistical information, investigation and survey information, digest and quotes used in an advertisement shall be factually *true and accurate*, and their sources mentioned. These rules have implications also on functional food marketing, where performance and use of goods is often mentioned, and where scientific information is often referred to. There are also special advertising rules on patented products in Article 11⁹⁸⁵.

According to Article 13, an advertisement shall be distinguishable, and make consumers identify it as an advertisement. The mass media may not publish advertisements in the form of news reports. An advertisement published through the mass media shall bear the advertisement mark to distinguish it from new items so that consumers may not be misled. In the Chinese Law, there is no direct rule on comparative advertisement. According to Article 12 of the Advertisement law, an advertisement may not belittle the goods or services of other producers and manufacturers or operators.

The European and Chinese general rules on advertising have much in common. Advertising must be clear, true, and accurate. Advertisements must be identifiable as such, and competitors may not be demeaned. Both sets of rules comply with the general marketing codes by the

⁹⁸² Article 3.

⁹⁸³ Article 4.

⁹⁸⁴ Article 5.

⁹⁸⁵ An advertisement involving patented goods or patented methods shall clearly indicate the patent number and type of patent. Products which have not been patented shall not be passed off as being patented. The use in advertisements of unsuccessful patent applications or those which have been terminated, nullified or invalidated is prohibited.

International Chamber of Commerce and there seems to be a global understanding on these fair marketing practices.

However, important cultural differences remain as parts of general national advertising laws. Article 7 of the Chinese Advertisement law is an example of Chinese cultural features:

“Advertisements may not contain any of the following:

1. the national flag, national emblem or national anthem of the People’s Republic of China,
2. the names of state organs or names of staff of state organs,
3. such words as the “state-level”, the “highest-level” or the “best”,
4. matters hindering social stability or endangering the safety of life or property, or harming the public interest,
5. matters hindering the public order or violating good social customs,
6. pornographic, superstitious, horrid, violent or unpleasant matters,
7. ethnic groups, racial, religious or sex discrimination matters,
8. matters hindering environmental and natural resources protection, and
9. matters that are prohibited by laws and administrative regulations.”

Parts of this list could not exist in a European directive as the Chinese concept of free speech is rather narrow, and matters harming social order and the state must be avoided. The Chinese interpretation of what is “pornographic” or “unpleasant” is also different from the European interpretation of what is considered indecent or immoral.

In addition to general rules applicable to advertising of all products, the Chinese Advertisement law includes special rules on medicine marketing. These will be discussed below.

5.2 General Rules on Food Marketing⁹⁸⁶

5.2.1 EU

5.2.1.1 Prohibition of Misleading Food Advertising

In the EU, the general food regulation⁹⁸⁷ is the basic law both with regard food safety and as regards food marketing. Article 8 regulates the protection of consumers’ interest. It states: “Food law shall aim at the protection of the interest of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

- (a) fraudulent or deceptive practices;
- (b) the adulteration of food; and
- (c) any other practices which may mislead the consumer.”⁹⁸⁸

⁹⁸⁶ This means rules other than those applicable to claims.

⁹⁸⁷ Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety.

⁹⁸⁸ This article reflects the same principle as Article 1 of the Misleading and Comparative Advertising Directive codified by 2006/114/EC/.

Article 16 of the Regulation concerns presentation. It is more precise than Article 8: “Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food and feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.” This statement is fairly comprehensive. It aims to cover all means of misleading the consumer. However, more specific provisions of food law are mentioned. These rules apply to special types of foods and are discussed below.

5.2.1.2 General Rules on Food Labelling

In addition to being cognisant with the rules on food advertising, a marketer must know what information he *must give* to consumers. In Europe, as in most countries, the *ingredient list* must appear on the package of a food product.⁹⁸⁹ Hence the first requirement for the marketer is to know what is in the food. *Nutrient information/nutrition labelling* (for example how much fat, lactose or vitamin C the product contains) is optional in Europe, if a nutrition claim is not presented. Where nutrition claims appear on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling will become compulsory.⁹⁹⁰

General food labelling⁹⁹¹ is governed by Directive 2000/13/EC⁹⁹², which is a codified version of Directive 79/112/EC. The directive concerns the labelling of foodstuffs to be delivered as such to the ultimate consumer and certain aspects relating to the presentation and advertising thereof⁹⁹³. It also applies to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers⁹⁹⁴. For the purpose of the Directive, ‘labelling’ means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document notice, label, ring or collar accompanying or referring to such foodstuff⁹⁹⁵.

Most of the provisions date back to 1978. One major recent amendment to the food- labelling directive was introduced in 2003. This amendment makes it obligatory for all ingredients to be indicated on the label. The new labelling rules particularly help consumers suffering from food allergies or consumers who wish to avoid eating certain ingredients for any other reason. The new rules foresee that all ingredients in foodstuffs will have to be included on the label and abolish the previous 25% rule which meant that it is was not obligatory to label the components of compound ingredients that make up less than 25% of the final food product.⁹⁹⁶

⁹⁸⁹ Ingredients must be listed in descending order in terms of total content.

⁹⁹⁰ Nutrient information is given per 100 g in Europe, or per serving.

⁹⁹¹ Specific labelling issues such as origin labelling or welfare labelling are not discussed here as they are not particularly relevant to functional foods.

⁹⁹² Directive 2000/13/EC of the European Parliament and of the Council 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

⁹⁹³ Article 1(1).

⁹⁹⁴ Article 1(2).

⁹⁹⁵ Article 1(3).

⁹⁹⁶ European Commission web page. http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm.

According to the European Commission, the evolution of both the foodstuffs market and consumers' expectations as to the information given has led to the need to update this legislation. That is why the Commission is currently preparing to modernise the law on food labelling⁹⁹⁷, among other rules on labelling of consumer products. According to DG SANCO⁹⁹⁸, they are focusing on "better regulation" as a means to contribute to achieving growth and jobs⁹⁹⁹.

The Commission is ready to rethink the entire labelling scheme. Benefits of simplifying and clarifying the structure and scope¹⁰⁰⁰ of the existing labelling legislation are weighed. The directive might for example be turned into a regulation¹⁰⁰¹. Commission suggested that maybe *food and non-food labelling* might be considered as a whole. *Prescription vs. flexibility* of the rules is also reconsidered. The Commission is also considering *self-regulation or co-regulation* in labelling issues¹⁰⁰². In developing labelling rules, the Commission must also think of how to deal with small and medium-sized enterprises (SMEs), as the costs of introducing labelling changes will generally be higher for SMEs.

As a result of a consultation process launched by the Commission in 2006, stakeholder views on labelling issues were received. The majority of respondents wanted food labelling and non-food labelling to be distinct. As one might imagine, *the food industry would like to see as few legislative requirements as possible*. The industry would prefer self-regulation as regards voluntary labelling, keeping rules on mandatory labelling in 'hard law'. Consumer organisations and organisations for health and animal welfare would like to see as many legislative requirements as possible. They do not trust self-regulation like codes of practice. Also, predictably, views of governments are between these extremes, as they must search for the right balance.¹⁰⁰³ Most stakeholders welcomed the new legislation to be in a form of regulation. The mandatory requirements currently listed under Article 3.1 of Directive 2000/13/EC were not questioned by stakeholders^{1004, 1005}.

⁹⁹⁷ Labelling: competitiveness, consumer information and better regulation for the EU. A DG SANCO Consultative Document February 2006.

⁹⁹⁸ DG SANCO is the Health and Consumer Protection Directorate General of the European Commission.

⁹⁹⁹ The Consultative Document 2006, 1. Consumer policy is a part of the Lisbon Strategy, where the EU is aiming to create growth and employment. See Commission press release: "A new Consumer Strategy: Consumers must lead the drive for growth and jobs." IP/07/256. Date: 27/02/2007.

¹⁰⁰⁰ Information that must be provided might for example be distinguished from information that should be available for the purchaser of the foodstuff. Labelling: competitiveness, consumer information and better regulation for the EU. A DG SANCO Consultative Document February 2006. Page 6.

¹⁰⁰¹ Labelling: competitiveness, consumer information and better regulation for the EU. A DG SANCO Consultative Document February 2006. Page 5.

¹⁰⁰² Labelling: competitiveness, consumer information and better regulation for the EU. A DG SANCO Consultative Document February 2006. Page 3. See chapter 2.2 on European hard law and soft law.

¹⁰⁰³ Summary of results for the consultation document on: "Labelling: competitiveness, consumer information and better regulation for the EU". December 2006. Directorate E – Safety of the Food Chain. Unit E4 – Food law, nutrition and labelling. Pages 4-5.

¹⁰⁰⁴ Summary of results for the consultation document on: "Labelling: competitiveness, consumer information and better regulation for the EU". December 2006. Directorate E – Safety of the Food Chain. Unit E4 – Food law, nutrition and labelling. Page 10.

¹⁰⁰⁵ Summary of results for the consultation document on: "Labelling: competitiveness, consumer information and better regulation for the EU". December 2006. Directorate E – Safety of the Food Chain. Unit E4 – Food law, nutrition and labelling. Pages 8-9.

In January 2008, the Commission proposed to put food labelling and nutrition labelling directives together in one legal instrument, a regulation¹⁰⁰⁶. The proposed rules include the requirement that the print size of the mandatory particulars on label must be at least 3 mm¹⁰⁰⁷. The draft Regulation also extends the current requirements for allergen labelling to cover non pre-packed food, including food sold in restaurants and other catering establishments¹⁰⁰⁸. Rules on origin labelling will also be specified to avoid situations where the consumer is misled for example by the fact that the raw materials come from one place and the manufacturing process takes place in another¹⁰⁰⁹. Nutrition declaration will also be mandatory, see the next chapter.

The proposal leaves room for Member States to promote additional national schemes provided they do not undermine the EU rules. While manufacturers or retailers could always use the EU's main nutrition labelling system, national schemes would offer food businesses an alternative way of discharging the labelling obligation. This kind of flexibility has already been criticised for creating barriers to trade.¹⁰¹⁰

5.2.1.3 Nutrition Labelling

The Nutritional Labelling Directive 90/496/EEC concerns nutrition labelling of foodstuffs to be delivered as such to the ultimate consumer. It also applies to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers.¹⁰¹¹ It does not apply to natural mineral waters or other waters intended for human consumption or to food supplements.¹⁰¹² The Directive applies without prejudice to the labelling provisions of Council Directive 89/398/EEC on foodstuffs intended for particular nutritional uses and specific Directives as referred to in Article 4 of that Directive¹⁰¹³.

For the purposes of the Directive, 'nutrition labelling' means any information appearing on labelling and relating either to the energy value or to the amount of the following nutrients: protein, carbohydrate, fat, fibre, sodium, and vitamins and minerals listed in the Annex¹⁰¹⁴ of the Directive and present in significant amounts.

The most important principle of the Nutritional Labelling Directive is:

- if nutrition claims are not presented, nutritional labelling is optional, and
- *if a nutrition claim appears* on labelling, in presentation or in advertising, with the exclusion of generic advertising, *nutrition labelling is compulsory*.¹⁰¹⁵

¹⁰⁰⁶ Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers. COM(2008) 40 final. Brussels, 30.1.2008.

¹⁰⁰⁷ Article 14(1) of the proposed Regulation.

¹⁰⁰⁸ Article 9 of the proposed Regulation: List of mandatory particulars. Allergens are listed in Annex II of the proposal.

¹⁰⁰⁹ Food labelling proposal 2008, page 9. Explanatory memorandum. 3.) Legal elements of the proposal.

¹⁰¹⁰ Warnock 2008.

¹⁰¹¹ Article 1(1).

¹⁰¹² Article 1(2).

¹⁰¹³ Marketing of these dietetic foods is discussed in the following chapter.

¹⁰¹⁴ The list of vitamins and minerals is updated according to a procedure set out in Art 10.

¹⁰¹⁵ Article 2.

The only nutrition claims permitted are those relating to energy and/or to protein, carbohydrate, fat, fibre, sodium, vitamins and minerals and to substances which belong to or which are components of a category of those nutrients. Vitamin and mineral claims are limited to those defined in the Annex of the Directive and if these are present in a significant amount. A significant amount is defined as 15 % of the recommended daily allowance.¹⁰¹⁶

As stated above, a nutrition claim triggers nutrition labelling. There are two alternatives for nutritional labelling. When the claim relates to energy value, protein, carbohydrates or fat, the amounts of all of these shall be given. When the claim is made for sugar, saturates, fibre or sodium, the amounts of all of these shall also be given.¹⁰¹⁷ Whenever a claim is made, the amounts of starch, polyols, mono-unsaturates, polyunsaturates, cholesterol, and vitamins or minerals that are listed in the Annex and that are present in significant amounts must also be given¹⁰¹⁸. There is one other additional requirement for nutritional labelling, which has to be abided by even if a claim is not made: If the amount of polyunsaturates and/or mono-unsaturates and/or the cholesterol rate are given, the amount of saturates must also be given. In this case, the amount of saturates is not considered to be a nutrition claim¹⁰¹⁹. In other cases where no claim is made, nutritional information can be given, as long as it is accurate.

Nutritional information shall be expressed per 100 g or per 100 ml. In addition, this information may be given per serving as quantified on the label or per portion, provided that the number or portions contained in the package is stated.¹⁰²⁰ The amounts mentioned are to be those of the food as sold. Where appropriate, this information may relate to the foodstuff after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption.¹⁰²¹ Information on vitamins and minerals must also be expressed as a percentage of the recommended daily allowance.¹⁰²²

According to the Commission, there is a need to revise the nutrition labelling directive to address fundamental issues relating to nutrition labelling¹⁰²³. Commission gathered stakeholder input on this subject in 2006. It has been suggested that nutrition labelling should be mandatory. At the moment, many companies are voluntarily providing the information (estimates suggest a range of between 30% and 85% for pre-packaged foods)¹⁰²⁴. Consumers are in favour of mandatory nutrition labelling, the industry isn't. Both sides and also member state governments might be willing to settle for a compromise solution. This would make nutrition labelling mandatory but grant derogations, create transitional measures and offer necessary flexibilities¹⁰²⁵. When discussing what should be on the nutrient list, the 'Big 4' (i.e.

¹⁰¹⁶ Article 3.

¹⁰¹⁷ Article 4(1-2).

¹⁰¹⁸ Article 4(3).

¹⁰¹⁹ Article 4(4).

¹⁰²⁰ Article 6(2).

¹⁰²¹ Article 6(4).

¹⁰²² Article 6 (5)(a).

¹⁰²³ Labelling: competitiveness, consumer information and better regulation for the EU. A DG SANCO Consultative Document February 2006, Page 7.

¹⁰²⁴ Labelling: competitiveness, consumer information and better regulation for the EU. A DG SANCO Consultative Document February 2006, Page 7.

¹⁰²⁵ Summary of results for the consultation document on: "Labelling: competitiveness, consumer information and better regulation for the EU". December 2006. Directorate E – Safety of the Food Chain. Unit E4 – Food law, nutrition and labelling. Page 15.

energy, protein, fat, carbohydrates) and the ‘Big 8’ (i.e. the Big 4 plus saturated fat, sugar, fibre and sodium) were most often mentioned¹⁰²⁶.

In January 2008, the Commission finally gave a proposal combining the current food labelling directive 2000/13/EC and the nutrition labelling directive 90/496/EEC. The proposal is for a Regulation of the European Parliament and of the Council on the provision of food information to consumers¹⁰²⁷. It is not surprising that the regulation form was chosen instead of a directive, see chapter 2.

The most controversial point in the proposal is the introduction of *mandatory labelling of key nutrients*. The proposal adopts the Guideline Daily Amount (GDA) approach instead of the traffic lights approach favoured by the UK’s Food Standards Agency and the European Consumer Association (BEUC).¹⁰²⁸ For example in Finland, the GDA approach was voluntarily adopted by the industry in 2007¹⁰²⁹.

According to Article 29(1) of the proposed Regulation, the nutrition declaration shall include the following:

- (a) energy value;
- (b) the amounts of fat, saturates, carbohydrates with specific reference to sugars, and salt.

These would need to be given per 100g or 100ml¹⁰³⁰ and also by reference to GDAs¹⁰³¹. According to Article 29(2) of the proposed Regulation, the nutrition declaration may also include the amounts of trans fats, mono-unsaturates, polyunsaturates, polyols, starch, fibre, protein, or certain vitamins and minerals. Trans fats would appear on nutrition declarations for the first time.

5.2.1.4 Marketing of Dietetic Foods

Foodstuffs for particular nutritional uses are also known as dietetic foods, defined in Directive 89/398/EC. Dietetic foods are foodstuffs which, owing their special *composition* or *manufacturing process*, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.¹⁰³² Above (chapter 4), we have already discussed the safety aspects of dietetic foods. Here we look at dietetic foods from a marketing perspective.

“A particular nutritional use must fulfil the particular nutritional requirements:

- (i) of certain categories of persons whose digestive processes or metabolism are disturbed; or

¹⁰²⁶ Summary of results for the consultation document on: “Labelling: competitiveness, consumer information and better regulation for the EU”. December 2006. Directorate E – Safety of the Food Chain. Unit E4 – Food law, nutrition and labelling. Page 16.

¹⁰²⁷ COM(2008) 40 final. Brussels, 30.1.2008.

¹⁰²⁸ Warnock 2008.

¹⁰²⁹ Elintarviketeollisuusliitto ry. Tiedote 7.2.2008.

¹⁰³⁰ Article 31(2) of the proposed Regulation.

¹⁰³¹ Article 31(3) of the proposed Regulation.

¹⁰³² Article 1(2)(a), Directive on Foodstuffs Intended for Particular Nutritional Uses, 89/398/EC. Foodstuffs for particular nutritional uses have their own fortification rules, set out in Commission Directive 2001/15.

- (ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or
- (iii) of infants or young children in good health.¹⁰³³

The first rule on dietetic food marketing is the permission to use the word ‘dietetic’. The products in sections (i) and (ii) may be characterised as ‘dietetic’ or ‘dietary’¹⁰³⁴. For normal products, the use of words ‘dietetic’ or ‘dietary’ is forbidden. This means that in the labelling, presentation and advertising of foodstuffs for normal consumption, the use of the adjectives ‘dietetic’ or ‘dietary’ either alone or in conjunction with other words, to designate these foodstuffs is prohibited. Also all other markings or any presentation likely to give the impression that a dietetic food is involved are prohibited for normal products.¹⁰³⁵ The second rule on dietetic food marketing is that for dietetic foods, *nutrition labelling is mandatory* regarding the amount of energy, protein, carbohydrates, and fat therein¹⁰³⁶.

Specific rules on specific dietetic foods are to be laid down by specific directives¹⁰³⁷. These groups¹⁰³⁸ are:

- instant formula and follow-on formula,
- processed cereal-based foods and baby foods for infants and young children,
- food intended for use in energy-restricted diets for weight reduction,
- dietary foods for special medical purposes (medical food),
- foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, and
- foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

Directives on sports nutrition and diabetes foods are still missing as previously stated in chapter 4. The special directives include marketing rules. For example in the directive on weight-loss foods, it is stated that “the labelling, advertising and presentation of the products concerned shall not make any reference to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety”¹⁰³⁹.

Drawing the line between ordinary foods with health claims and foodstuffs for particular nutritional uses has come up in different forms. Foods with health effects appear to be following two separate marketing lines: as normal foods and as dietetic foods. It is often possible that a foodstuff that has scientifically proven health-promoting effects will go under the definition of dietetic foods. Where a special diet is obeyed, it is often to reduce the risk of becoming ill. For example, persons with high cholesterol can use products with plant sterols to lower

¹⁰³³ Article 1(2)(b).

¹⁰³⁴ Article 2(1).

¹⁰³⁵ Art. 2(2).

¹⁰³⁶ If the product contains less fat than 50 kJ/100g, only energy content has to be given. The long list of nutrition labelling is mandatory if you want to give the amount of sugar, fibre, sodium, or saturated fats as something else than a nutritional special feature of the product. See previous chapter on ‘short’ and ‘long’ lists in nutrition labelling.

¹⁰³⁷ According to Article 4.1 of the Directive on dietetic foods.

¹⁰³⁸ As listed in Annex I of the Directive on dietetic foods.

¹⁰³⁹ Article 5(3).

the cholesterol levels in blood serum. This would be a particular nutritional use. For these products, product-specific risk reduction claims also seem appropriate, as the products lower the risk of coronary heart disease¹⁰⁴⁰.

Certain functional foods can be classified as dietary foods if they are specially formulated and/or provide a part of the population health benefits over and above their normal nutritional values. Certain functional foods clearly are not dietary foods, as they provide the whole population with health benefits over and above their normal nutritional values.¹⁰⁴¹ This means that a product with a health claim such as “antioxidant” could not be classified as a dietetic food, and that a product with a health claim such as “lowers blood pressure” could.

Sometimes it is difficult to distinguish between “ordinary dietetic food” and medical food¹⁰⁴². Specification of benefits can be a criterion to determine this. Since functional foods are by definition a part of a normal diet and they do not need any medical supervision, they are clearly distinguished from medical foods. If a certain food can provide distinctive dietary requirements to a patient requiring medical supervision, it can be sold as a medical food. If it can provide health benefits to a specified group of people or to people in general, it should be sold as either an ordinary dietetic food or an ordinary food with a health claim.¹⁰⁴³

As stated above in chapter 4, the directive on dietetic foods establishes a notification system. The primary purpose of the notification system is not to verify the claim but rather to ensure that the food in question is distinguishable from foodstuffs for normal consumption and is suitable for the claimed nutritional purpose. However, several national administrations have indicated that they also verify the claim being made. Under the Directive, companies have to submit a model of the label used and may also be asked to produce scientific work and data¹⁰⁴⁴.

5.2.1.5 *Marketing of Food Supplements*

With regard to marketing information on food supplements¹⁰⁴⁵, the Directive 2002/46 details rules for their labelling. The marketer must provide information on the vitamin and mineral content, and on the proper use of the product. The name under which food supplements are sold shall be “food supplement”¹⁰⁴⁶.

The labelling shall bear the following particulars:

¹⁰⁴⁰ Swedish report 2001, 34.

¹⁰⁴¹ Kwak – Jukes 2000b, 111.

¹⁰⁴² The definition of foodstuffs for special medical purposes was given above in chapter 4.

Medical foods are a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites. Directive 1999/21/EC Article 1(2)(b).

¹⁰⁴³ Kwak – Jukes 2000b, 112.

¹⁰⁴⁴ Article 9.

¹⁰⁴⁵ See definition of ‘food supplement’ above in chapter 4.

¹⁰⁴⁶ Article 6(1).

- (a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;
- (b) the portion of the product recommended for daily consumption;
- (c) a warning not to exceed the stated recommended daily dose;
- (d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
- (e) a statement to the effect that the products should be stored out of the reach of young children.¹⁰⁴⁷

Otherwise, the general marketing rules and the general food marketing rules apply. Marketing must not be misleading, and unfair commercial practices such as pyramid schemes are prohibited. Like foods in food form, food supplements also need to include an ingredient list, including statements on common allergens.

5.2.1.6 *Marketing of Novel Foods*

There are special labelling requirements for novel foods. According to Regulation 258/97/EC /on novel foods, the final consumer must be informed of:

- (a) any characteristic or food property (such as composition, nutritional value or nutritional effects, or intended use of the food) which renders a novel food or food ingredient *no longer equivalent* to an existing food or food ingredient¹⁰⁴⁸. In this case, the labelling must indicate the properties modified, together with the method by which the property was obtained.
- (b) the presence of material which is not present in an existing equivalent foodstuff and which may have *implications for the health* of certain sections of the population;
- (c) the presence of material which is not present in an existing equivalent foodstuff and which gives rise to *ethical concerns*.¹⁰⁴⁹

This means labelling has to give information on substances that traditional, equivalent products do not have, for example on allergenic proteins, or on materials that may cause ethical insecurity in some consumer groups. Information on changed composition, nutritional quality or purpose of use compared to normal product must also be given. In the absence of an existing equivalent food or food ingredient, appropriate provisions shall be adopted where necessary in order to ensure that consumers are adequately informed of the nature of the food or food ingredient¹⁰⁵⁰. When authorising a product, the labelling question is resolved at the same time. The product labels are customized and accepted for each product separately.

¹⁰⁴⁷ Article 6(3).

¹⁰⁴⁸ “A novel food or food ingredient shall be deemed to be no longer equivalent ... if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.”

¹⁰⁴⁹ Article 8(1).

¹⁰⁵⁰ Article 8(2).

With novel food labelling, one should notice that mandatory statements required by Community law shall not be considered as claims. They are thus not in the scope of the Nutrition and Health Claim Regulation, which covers only claims made on a voluntary basis. This applies for example to statements on cholesterol for products containing phytosterols, phytosterols, or their esters.¹⁰⁵¹ The Commission Regulation 608/2004/EC¹⁰⁵² requires that the labelling of these products includes a statement that the product is intended exclusively for people who want to lower their blood cholesterol level¹⁰⁵³.

According to the proposed Regulation on novel foods, a Community list of authorised novel foods will be created. The decision to include a food on the Community list shall include, where appropriate, specific additional labelling for novel foods sold to the consumer¹⁰⁵⁴.

5.2.1.7 Marketing of GMO Food

Regulation 1830/2003/EC concerns the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. In Europe, GMO food must be labelled as such.

“For products consisting of or containing GMOs, operators shall ensure that:

- (a) for pre-packaged products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ appear on a label;
- (b) for non-pre-packaged products offered to the final consumer the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ shall appear on, or in connection with, the display of the product.”¹⁰⁵⁵

This means the labelling requirement applies to products such as flour, oils, and glucose syrups if they are from a GMO source, such as GM soy or maize. Products produced with GMO technology, cheese produced with GMO enzymes, for example, does not have to be labelled. Neither do products such as meat, milk and eggs from animals fed on GMO animal feed.¹⁰⁵⁶ Consumers have expressed complaints and demanded to know about GMO use in the whole production chain.

Conventional products, i.e. products created without recourse to genetic modification, may be accidentally contaminated by GMOs during harvesting, storage, transport or processing¹⁰⁵⁷.

¹⁰⁵¹ Scientific Committee on Food Safety and Animal Health. Guidelines on the Implementation of the Regulation 1924/2006/EC. December 2007. Page 5.

¹⁰⁵² Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytosterols and/or phytosterol esters.

¹⁰⁵³ Article 2(3). Article 2 also stipulates other important mandatory statements that have to be used on the labels to inform the consumers on the safe and proper use of these products.

¹⁰⁵⁴ Novel food proposal 2007, page 7.

¹⁰⁵⁵ Article 4(B)(6).

¹⁰⁵⁶ UK Food Standards Agency. GM Labelling. 2 August 2007.

¹⁰⁵⁷ European Commission web page. Questions and answers on the regulations of GMOs in the European Union. Page 16. http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf.

Where GMOs are present in a proportion no higher than 0.9%, these products are *exempted* from the labelling requirement, provided that traces of (authorised) GMOs are adventitious or technically unavoidable¹⁰⁵⁸. This is the case when operators demonstrate to the competent authorities that they have taken adequate measures to avoid the presence of this material¹⁰⁵⁹.

5.2.1.8 Marketing of “Junk Food”

In Europe, discussions on advertising of so-called junk food have been going on. In the UK, advertising of foods and drinks with high fat, salt and sugar content has been restricted since June 2007 and these foods cannot be marketed during television programming aimed at under sixteen-year-old viewers. The UK Office of Communications¹⁰⁶⁰ also considered forbidding all food advertising aimed at children.¹⁰⁶¹

The UK food and drink industry had previously self-regulated advertising: some had withdrawn from advertising to younger children. However, the food industry was “shocked” when the Ofcom restrictions came to its attention. They would have preferred the restriction to only apply to programs for children up to the age of nine as had been discussed. They would have preferred longer transition periods. It was revealingly noted, that the restrictions “quite possibly affect sales of many popular products”.¹⁰⁶² Because the very goal of these restrictions is to limit children’s consumption of junk food, they target sales reduction. We could ask what the real goal of self-regulation was; to postpone regulation?, to build a better company image? Also the demand for longer transition periods seems ungrounded. It does not take years to stop advertising during children’s programs. The restrictions create a real incentive to reformulate existing products and to develop new products.

The US consumer lobby groups say that Americans could use the UK way as an example. They say voluntary ad restrictions in the US are a proven failure and that the UK approach is far more effective. They also say that the US voluntary measures are promulgated merely to forestall government action and to make life easier for advertisers.¹⁰⁶³ This is unfortunately often the case with self-regulation: the industry will not be the first to impose stringent limitations on itself.

More and more people are of the view that unhealthy food should be treated the same way as tobacco and alcohol. It is clear to practically every consumer that poor diet causes health problems equivalent to those caused by tobacco and alcohol. The food industry might claim that it is their constitutional right to market their legal products. But parents might claim that it is their children’s constitutional right not to receive marketing material on harmful products. Junk food can still be *sold* to children. It would be radical indeed if McDonalds, Burger King, and KFC would stop selling to children altogether.

¹⁰⁵⁸ Article 4(C) (8).

¹⁰⁵⁹ European Commission web page. Questions and answers on the regulations of GMOs in the European Union. Page 16. http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf.

¹⁰⁶⁰ Ofcom is the independent regulator and competition authority for the UK communications industries. www.ofcom.org.uk.

¹⁰⁶¹ Fletcher 2006.

¹⁰⁶² Warnock 2006 according to Fletcher 2006.

¹⁰⁶³ This is claimed to be part of the Bush Administration strategy oriented to protecting business, not consumers. Jacobson 2006.

Marketing restrictions on junk food do not directly affect functional foods, but are interesting as they are a step towards the regulatory direction that is anti-junk-food. This kind of “nutritionist’s approach” to regulation is favourable to developers of functional foods. This approach already manifests itself in the nutrition and health claim regulation, which allows claims to be made only if the nutritional profile of the product is under the agreed limit. It has also been suggested that unhealthy foods should be taxed more heavily than others, or that people with diet related diseases should pay for these diseases themselves. Junk food advertising could also be prohibited altogether, also for adults. In the future, drastic measures like this might be considered. The producers and restaurants would be forced to reformulate their product palettes and menus so that every burger and candy bar had a less-fat less-sugar alternative or replacement. This could create more market potential for functional foods.

5.2.2 China

5.2.2.1 General Rules on Labelling and Advertising

Like in Europe, there is certain mandatory information that must be given to consumers on foods. Article 21 of the Food Hygiene Law concerned food labelling:

“Any standardized packaged food or food additive must, according to the requirements for different products, have

- the name of the product,
- the place of manufacture,
- the name of the factory,
- the date of manufacture,
- the batch number (or code number),
- the specifications,
- the formula or principal ingredients,
- the date of expiration for guaranteed quality,
- the method of consumption or use, and
- other such information.

The product description for any food or food additive shall not contain exaggerated or false advertising. The label of the food package must be clearly printed and easy to read. Foods sold on domestic markets must have labels in the Chinese language.”

5.2.2.2 Nutrition Labelling

Until recently, nutrition labelling was not nationally regulated in China. According to a new regulation, Administrative Measures on Food Nutrition Labelling, China requires basic nutritional labelling on all food packaging from May 1, 2008. Labels are required to show how much protein, fat, carbohydrate and sodium is in a food, and may also show the cholesterol,

sugar and vitamin content. The rules stress that nutritional labelling must be accurate and objective.¹⁰⁶⁴ The same regulation covers nutrition claims.

China has worked together with ASEAN¹⁰⁶⁵ countries¹⁰⁶⁶ to remove barriers to food and beverage trade.¹⁰⁶⁷ Promoted by ILSI¹⁰⁶⁸ South East Asia Region, these countries have standardised nutrition labelling and scientific substantiation of claims¹⁰⁶⁹. Codex guidelines on nutrition labelling (amended 2006) have been used as reference.¹⁰⁷⁰

It seems that all over the world, harmonisation of the laws is seen as an important tool to facilitate food trade. However, countries are mainly focused on neighbouring countries when harmonising the rules. In Europe, the main goal is to promote free trade in the European Community. Still, nutrition labelling is based on similar principles in Europe, China, and for example the United States. This is because of makers of international standards, here particularly Codex and ILSI. For instance, the Codex guidelines are fairly identical to national regulations regarding nutrition labelling and nutrition claims.

5.2.2.3 *Marketing of GMO Foods*

China started implementing new rules on GMOs in 2002. GMO foods have their special labelling requirements¹⁰⁷¹. As discussed above in chapter 4, the Ministry of Health administers the list of authorised GMOs. The Agricultural GMO Labelling Regulations prohibit sales and imports of listed GMOs (such as soybeans, corn, rapeseed, cotton seed, and tomatoes) unless they are clearly labelled as genetically modified products.¹⁰⁷² This is to ensure traceability of GMOs and to protect consumers' right to information.

5.3 **Claims in Food Marketing: Nutrition Claims, Health Claims**

5.3.1 **Claims as Statements of Efficacy**

The meaning of the word 'claim' is generally well understood. A widely accepted definition of a 'claim' is that of Codex Alimentarius (1991). This definition applies to claims in food marketing. Claim is defined as "any representation, which states, suggest or implies that a

¹⁰⁶⁴ Reuters Beijing January 11 2008.

¹⁰⁶⁵ Association of Southeast Asian Nations.

¹⁰⁶⁶ Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam.

¹⁰⁶⁷ See: "Memorandum of Understanding between the Association of Southeast Asian Nations and the Government of the People's Republic of China on Strengthening Sanitary and Phytosanitary Cooperation. Singapore, 20 November 2007."

¹⁰⁶⁸ International Life Sciences Institute.

¹⁰⁶⁹ According to ILSI South East Asia Region, they "promote the development of a harmonized approach for food safety standards". ILSI South East Asia Region web page at: <http://southeastasia.ilsa.org/about/>.

¹⁰⁷⁰ Chinese Nutrition Society. Web page at: <http://www.cnsoc.org/asp-bin/GB/?page=8&class=104&id=455>.

¹⁰⁷¹ Provisions for Labelling Administration of Genetically Modified Farm Products (MOA regulation; Order No. 10; Promulgation Date: 2002-01-05; Effective Date: 2002-03-20.

¹⁰⁷² Food Navigator news. <http://www.foodnavigator.com/news/ng.asp?id=43552-gmo-labels-launched>.

food has certain characteristics relating to its origin, nutritional properties, nature, production, processing, composition, or any other quality”.¹⁰⁷³ According to the new EU definition, “claim” in connection to food marketing means “any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics”¹⁰⁷⁴.

Food claims, and particularly those related to nutrition and health, have become a legally interesting question mainly because of functional foods.¹⁰⁷⁵ With medicines, the rules on efficacy and claims have been in place for a long time. Medicines have to be effective, and are therefore tested regarding their final health effects in human subjects. The clinical tests are randomised and controlled. It is clear that medicines are marketed by telling what disease they treat.¹⁰⁷⁶ Functional foods have changed the picture. Now also foods can be effective in fighting disease or keeping one healthy. This means *efficacy and claims of foods must be regulated*. A product is generally considered effective, if it is scientifically proven to have a positive impact on health.

In functional food marketing, claims are often related to nutritional science. A key issue on science-related marketing claims is the level of scientific proof required including the system to substantiate the claims. The substantiation system shall not become a disincentive for product developers, and it needs to build product acceptance by consumers. The process for the establishment, verification, and use of claims should be scientifically sound and credible. At the same time, the process should be flexible and pragmatic.¹⁰⁷⁷

There are different types of health effects, and different types of marketing claims. Claims on foodstuffs and medicines can be divided in three main categories, two of which belong to foods and one to medicines:

Nutrition claims simply state nutritional facts without directly referring to health problems. Nutrition claims are scientifically and politically rather simple compared to health claims.

Health claims state that a product enhances health or reduces the risk of a disease. Health claims are legally the most difficult claim category. It is difficult to determine which health effect should enable the making of which claim, and at the same time to draw the line to medicinal claims.

Medicinal claims state that a product might *cure, treat or prevent* a disease. In law, medicinal claims are reserved for medicinal products and are thus prohibited on foods.

Nutrition claims, health claims, and medicinal claims are factual claims, which the marketer has to be able to substantiate. This is in comparison to claims that are regarded as common appraisals, like claiming your product is “great” or equivalent.

¹⁰⁷³ Codex General Guidelines on Claims, 31.

¹⁰⁷⁴ Nutritional and Health Claim Regulation, Article 2(2)(1).

¹⁰⁷⁵ Other types of claims in modern food marketing relate, for example, to ethical and environmental questions.

¹⁰⁷⁶ We will return to medicine marketing below.

¹⁰⁷⁷ Richardson 1998, 205.

5.3.2 Codex Guidelines on Nutrition and Health Claims

At international level, the Codex Alimentarius adopted Guidelines on Nutrition Labelling in 1985, General Guidelines on Claims in 1991, and Guidelines for the Use of Nutrition Claims in 1997. In 2004, the latter was amended to include health claims.

According to Guidelines on Nutrition Labelling¹⁰⁷⁸, and Guidelines for Use of Nutrition and Health Claims¹⁰⁷⁹,

“nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims:

- (a) the mention of substances in the list of ingredients;
- (b) the mention of nutrients as a mandatory part of nutrition labelling;
- (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.”

According to Guidelines for Use of Nutrition and Health Claims, nutrition claims are divided into nutrient content claims and nutrition comparative claims. Nutrient content claims describe the level of a nutrient contained in a food, for example, “source of calcium”, “rich in fibre”, “low in fat”. Nutrient comparative claims compare the nutrient levels and/or energy value of two or more foods, for example “reduced”, “more than”, “increases”¹⁰⁸⁰.

According to Guidelines for Use of Nutrition and Health Claims, *“Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.”*¹⁰⁸¹ Health claims include the following:

- nutrient function claims,
- other function claims, and
- reduction of disease risk claims.

Nutrient function claim is a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.¹⁰⁸² This means that *nutrient function claims are regarded both as nutrition claims and as health claims*. The reason for this rather confusing regulatory solution is that nutrient function claims were previously defined as the third type of nutrition claims. When health claims were included in the Guidelines, nutrient function claims were transferred under health claims without changing their definition.

¹⁰⁷⁸ Codex Alimentarius Guidelines on Nutrition Labelling. CAC/GL 2/1985. Amended 2003 & 2006. Section 2.4.

¹⁰⁷⁹ Codex Alimentarius Guidelines for Use of Nutrition and Health Claims. CAC/GL 23/1997, Rev. 1/2004. Section 2.1.

¹⁰⁸⁰ Sections 2.1.1. and 2.1.2.

¹⁰⁸¹ Section 2.2.

¹⁰⁸² Section 2.2.1.

According to current Guidelines, claiming what a nutrient *does* is evaluated according to the same principles as other health claims.

Other function claims concern “specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body”. Such claims relate to “a positive contribution to health or to the improvement of a function or to modifying or preserving health”.¹⁰⁸³

Reduction of disease risk claims “relate the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition”. Risk reduction is, “significantly altering a major risk factor(s) for a disease or health-related condition”. The Guidelines clarify the difference between risk reduction and prevention: “Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.”¹⁰⁸⁴

On health claims, Codex Guidelines require scientific substantiation of the claim, adequate labelling to instruct the consumer, and that the health benefit arises from the consumption of a reasonable quantity of the food in question. They also require that national authorities should ban health claims on foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition.¹⁰⁸⁵ This means that the food should be healthy as a whole.

When drafting European claim legislation, “due consideration” was given to the definitions and conditions set in the above-mentioned Codex Guidelines¹⁰⁸⁶. European definitions of ‘nutrition claim’ and ‘health claim’ are similar to the Codex definitions. The European ‘nutrition profile’ requirement corresponds to the Codex principles, and European regulation also separates between function claims and disease risk reduction claims. However, the separation between nutrient function claims and other function claims was not adopted from Codex.¹⁰⁸⁷ The Chinese have also followed Codex guidelines in their 2008 regulation on nutrition labelling and claims¹⁰⁸⁸.

5.3.3 EU Rules on Nutrition and Health Claims

5.3.3.1 Regulation Background: Prohibition of Medicinal Claims

In the European Union, the question of health claims was obscure for a long time. According to the Food Labelling Directive 2000/13/EC, medicinal claims are prohibited. Member States interpreted this prohibition on making medicinal claims on the basis of national tradition, which

¹⁰⁸³ Section 2.2.2.

¹⁰⁸⁴ Section 2.2.3.

¹⁰⁸⁵ Section 7.

¹⁰⁸⁶ Regulation 1924/2006/EC, preamble 7.

¹⁰⁸⁷ We will return to the European claim legislation in the next chapter.

¹⁰⁸⁸ Nutraingredients.com news 13 May 2008 at <http://www.nutraingredients.com/Regulation/China-takes-big-step-forward-in-nutrition-labelling>.

lead to legal uncertainty. Literal interpretations of legal texts prevailed in some Member States, and an approach based on the perceived spirit of the legislation was applied in others.¹⁰⁸⁹

According to Article 2(1) of the Food Labelling Directive,

“The labelling and methods used must not:

- (a) be such as could mislead the purchaser to a material degree, particularly:
 - (i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production;
 - (ii) by attributing to the foodstuff effects or properties which it does not possess;
 - (iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;
- (b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of *preventing, treating or curing a human disease*, or refer to such properties.”

Similarly, according to the Directive on dietetic foods¹⁰⁹⁰, the labelling and the labelling methods used, the presentation and the advertising of the products must not attribute properties for the prevention, treatment, or cure of human disease to the products covered by the directive or imply such properties. The prohibition of medicinal claims is also repeated in the food supplement directive 2002/46/EC¹⁰⁹¹: “The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties”. This means the same rules apply to all foods: medicinal claims are prohibited.

The prohibition of medicinal claims is absolute, regardless of whether the substance of the claim is true. The absolute prohibition is founded on the state of scientific knowledge at the time of the formulation of the original Directive 79/112/EEC, over 20 years ago. Since then scientific knowledge of the relationship between diet and health has advanced considerably. No direction is given in the Directive on health claims, which lie in-between nutrition claims and medicinal claims. This is because in 1979, food was clearly seen as nutrition. The Food Labelling Directive contains a provision¹⁰⁹² according to which the Commission shall come up with a non-exhaustive list of types of claims that should be prohibited or restricted, but all attempts at developing more detailed legislation on claims over the past years failed. Coppens and al. were of the view that unambiguous definitions for foodstuffs and medicinal products should be set, disease risk reduction claims should be allowed on foods, and medicinal claims should be left to medicines.¹⁰⁹³

The legislative stalemate at European level acted as a stimulus to national authorities to produce quasi-legal ‘guidelines’ and ‘voluntary agreements’. These initiatives were generally regarded as stopgap measures, until legislation was to be adopted at the EU level.¹⁰⁹⁴ For

¹⁰⁸⁹ Coppens et al. 2001, 141.

¹⁰⁹⁰ Article 6(1).

¹⁰⁹¹ Article 6(2).

¹⁰⁹² Article 2(2).

¹⁰⁹³ Coppens et al. 2001, 140.

¹⁰⁹⁴ EU Food Law August 2001, 11.

example Sweden, the UK, and the Netherlands developed their systems for evaluating health claims, and also the Finnish Food Agency provided information on their interpretation of the Food Labelling Directive. This was in the form of Health Claim Guidelines¹⁰⁹⁵ of 2002, a piece of soft law by the Food Agency.

The situation from the 1990's to 2006 was that European health claim regulation varied from non-existent legislation implying totally prohibited claims, to non-existent legislation representing widely allowed claims, to allowed but strictly regulated claims. It was considerably more difficult to get a functional food product on the market in for example Germany, Italy or Switzerland than it is in the UK or Sweden¹⁰⁹⁶. Hill & Knowlton found in their study concluded in 2000 that the most liberal approach regarding health claims in the EU was in Finland, France and the UK. The most restrictive were Austria, Belgium, Germany, Italy, Luxembourg and Portugal. The rest, i.e. Sweden, Denmark, Holland, Spain, Ireland, and Greece share the middle ground.¹⁰⁹⁷ A marketer needed to get acquainted with the practice in each country. The law on food claims was simultaneously too strong and too weak: prohibiting some important legitimate claims, while tolerating others, which were misleading and unsubstantiated¹⁰⁹⁸.

In Finland, the distinction between disease risk reduction and prevention was acknowledged, and all types of health claims were allowed. Disease risk reduction claims were, however, not regulated by the Foodstuffs Act itself but its preparatory materials, supplemented by soft law guidelines. A government's proposition to law of the year 2001¹⁰⁹⁹ set the rules on disease risk reduction claims: The health effect must be scientifically proven, and the marketer must give information on the importance of total diet, and claim-related information on the composition of the product¹¹⁰⁰. According to Health Claim Guidelines, the scientific evidence to back up the health claim must be on the product as sold. The Economy Committee pointed out that prevention and disease risk reduction are not far apart¹¹⁰¹.

The explanation concerning disease risk reduction claims was left out of the law itself, as the Finnish government expected a change in the Food Labelling Directive and postponed reforms until the anticipated amendment of the Directive. The Finnish regulators also referred to Codex guidelines and to CIAA proposals.¹¹⁰² In other words, Finns were confident that disease risk reduction claims would be allowed in the EU, but they did not dare change the Foodstuffs Act just yet.

In the meantime, the scientific consensus underlying health claims for foods was investigated by International Life Science Institute (ILSI) Europe. The conclusion of the EU-funded concerted action of Functional Food Science in Europe, FUFUSE, was the Consensus Document on Scientific Concepts in Functional food in Europe. The consensus document focused mainly on scientific and technological aspects of functional foods, but also mentioned claims. The ILSI document supported the development of enhanced function claims and disease risk reduction claims.¹¹⁰³

¹⁰⁹⁵ In Finnish: Terveysväitteiden valvontaopas. The Guide is only available in Finnish.

¹⁰⁹⁶ Food Engineering & Ingredients, October 2001, 18.

¹⁰⁹⁷ Hill & Knowlton 2000, 33.

¹⁰⁹⁸ Winkler 1998, 192.

¹⁰⁹⁹ HE 73/2001: Hallituksen esitys Eduskunnalle laiksi elintarvikelain 6 ja 24 §:n muuttamisesta.

¹¹⁰⁰ HE 73/2001.

¹¹⁰¹ Talousvaliokunnan mietintö 9/2001.

¹¹⁰² In the proposition to law, HE 73/2001.

¹¹⁰³ Diplock et al. 1999, S24.

The ILSI/EU concerted action proposed a scientific basis to claims: markers should be classified according to their relationship to the target function or disease endpoint. If evidence is based on functional markers, meaning markers of target function or biological response, a function claim might be justified. If evidence were based on an intermediate endpoint marker of disease, a disease risk reduction claim would be justified. In the latter case, the intermediate endpoint marker would have to be shown to be significantly and consistently modulated by the food product.¹¹⁰⁴

Heasman and Mellentin criticised the ILSI project. They said the scientists should have utilised research evidence from the social science and policy literatures when trying to develop a communication and health claim policy. Heasman and Mellentin claimed that the ILSI project produced outstanding review of the science in relation to functional foods, but in the final consensus document where the authors mapped out a policy and communications strategy for health claims and functional foods, they made a serious omission. They should have used academic research in the areas of communications, social marketing and public health practice, but they acted as though empirical and theoretical work in these areas was non-existent.¹¹⁰⁵

After the FUFOSSE program, ILSI Europe and the EU Commission started in 2001 a European network program PASSCLAIM. The aim of this program was to assess the research on functional foods, their health effects and the *claims* made on them. Scientific experts, regulators and industry took part in the program, and the results were presented in 2003. The PASSCLAIM program produced models of utilising clinical nutrition research and communicating the results to consumers.¹¹⁰⁶

*Council of Europe*¹¹⁰⁷ also took part in the debate and published in July 2001 a technical document giving Guidelines Concerning Scientific Substantiation of Health-Related Claims for Functional Foods. The document was given for debate in the European Parliament. The Council of Europe guidelines divide health-related claims in two: enhance-function claims and reduction of risk of disease claims. According to the paper, both enhanced function claims and disease risk reduction claims can be either generic or product-specific. Generic claims are based on a consensus in the scientific community regarding a diet-disease relationship. The claim can be used for any product provided that it fulfils certain compositional criteria. Product-specific claims, on the other hand, imply that the food product per se has certain physiological effects, which are observed when the food product is consumed in realistic amounts.¹¹⁰⁸

¹¹⁰⁴ Diplock et al., S25.

¹¹⁰⁵ Heasman – Mellentin 2001.

¹¹⁰⁶ Salminen – Mykkänen 2002, 34.

¹¹⁰⁷ The Council of Europe is a political organisation, which was founded on 5 May 1949 by ten European countries in order to promote greater unity between its members. It had 47 member states in 2008. The main aims of the organisation are to reinforce democracy, human rights and the rule of law and to develop common responses to political, social, cultural and legal challenges in its member states. The Council of Europe adopts European Conventions and agreements, which create the basis for a common legal space in Europe. Council of Europe web page at: http://www.coe.int/T/e/Com/about_coe/.

¹¹⁰⁸ Guidelines, 10.

According to Council of Europe guidelines, the *scientific substantiation* should be based on all data available (including experimental studies), but it should primarily be based on the results of well-designed human studies with the food or the nutrient, the component or the ingredient in the proposed food. These studies include observational, epidemiological, and, most importantly, nutrition intervention studies. The studies should be conducted according to the generally recognised principles of good practices.¹¹⁰⁹ This means that Council of Europe suggested a similar system to drug approval.

Communication of the health benefits to the consumer should inform on the quality of a particular food, but it should also play an education role. This education should concern especially the importance of adequate nutrition and the relationships between diet and well-being and between diet and disease risk.¹¹¹⁰ The suggested precise rules on communication of health-related claims were the following:

- trigger nutrition labelling,
- be truthful, unambiguous and understandable,
- make clear that the health-related claim applies only to the functional food consumed in the context of a total dietary pattern,
- not encourage over-consumption of a given food product to the detriment of others,
- include information of the quantity of the functional component or ingredient,
- include information on the target group or potentially vulnerable segment of the population if appropriate,
- include information on how to consume or use the functional food to obtain the claimed effect if appropriate.¹¹¹¹

Communication of health-related claims should also include the *documentation* of the scientific evidence behind the claims. Such documentation should:

- refer to the process of scientific substantiation and its principles,
- be based on, but not misinterpreting or overemphasising, the scientific substantiation,
- give a clear and truthful summary of the appropriate scientific data,
- describe how the scientific data supporting the health-related claim has been collected and evaluated,
- explain the plausibility in terms of scientific knowledge, and
- indicate where and how the dossier should be available to health professionals and research scientists.¹¹¹²

¹¹⁰⁹ Guidelines, 9.

¹¹¹⁰ Guidelines, 15.

¹¹¹¹ Guidelines, 15-16.

¹¹¹² Guidelines, 16.

The European Food and Drink Industry, CIAA¹¹¹³, created its own code of practice on the use of health claims. The code was developed to help manufacturers prepare the documentation necessary for the substantiation of health claims and to establish guidelines for the communication of health claims to consumers. CIAA said that legal framework governing claims was incomplete and inflexible. Regulations were applied differently from one Member State to another, and Codes of Practice existed in some Member States. In order to achieve a level playing field throughout the EU, CIAA believed that the use of a single set of guidelines adhered to by the whole European Food and Drink Industry would contribute to reducing barriers to trade pending clarification or change in the legislation.

The CIAA code applied to the use of health claims in labelling, advertisement and promotion of foods without prejudice to specific regulations, which exist for certain categories of food. “The code addresses neither nutrition claims, already defined by Codex Alimentarius nor dietetic claims as defined by EU legislation and Codex Alimentarius nor medical claims.” Nutrition and medicinal claims never really were a problem: the problem was health claims, because they are for products that are genuinely something between foods and medicines. Health claim is defined as ‘any claim establishing a relation between a food or a constituent of that food and health whether it is good health or a condition related to health or disease’.

The CIAA code recognised two types of health claims: enhanced-function claims and disease risk reduction claims. These are the same types that were also recognised by the ILSI project and the Council of Europe guidelines.

General Principles of the Code are summarised in the following:

- Communication of health claims should be in line with the *scientific substantiation*. It should be truthful and must not mislead, exaggerate or deceive either directly or indirectly.
- The claim should indicate an appropriate amount of intake required in order to obtain the desired effect.
- Health claims should be justified in the context of the whole diet and must be applicable to the amount of food normally consumed.

The more specific rules on communication are the following:

- The likely consumer perception of the health claim should be taken into account.
- Health claims should be complete, truthful and not misleading.

¹¹¹³ According to the CIAA (Confédération des Industries Agro-Alimentaires de l’UE, Confederation of the Food and Drink Industries of the EU) they are “the official mouthpiece of the food and drink industry in the European Union on issues common to the whole food and drink industry”. They describe their actions as follows: “CIAA is the favoured partner of the EC institutions. CIAA is composed of affiliated national federations, European sector associations and European food and drink companies grouped as an association. CIAA provides expertise within its expert groups and policy committees, which comprise manufacturers from all the countries of the European Union. CIAA establishes policy guidelines, which are aimed at a Community or international audience. CIAA has influence over the legislative process of the Community institutions and international organisation and it executes policy guidelines via its secretariat in Brussels.” For example the Finnish Food Industry Association (Elintarviketeollisuusliitto) is a member of CIAA.

- Health claims should only be made for a food as part of a total dietary pattern and should not encourage over-consumption of a given food to the detriment of others.
- Health claims should be consistent with the nature and scope of the evidence.
- Health claims should not denigrate other foods or imply that other foods cannot contribute to a healthy diet.
- There must be no implications that the food for which a claim is made is the only way to reduce the risk of a disease or illness.
- Channels other than the label can usefully complement the information on the product.

The more specific rules on substantiation are summarised in the following:

The collected evidence must show that the consumption of the food can result in the health effect that is claimed:

- In those cases for which scientific consensus exist, *bibliographic evidence* will normally be sufficient.
- For other claims the extent of the scientific evidence required should be determined on a *case by case basis* and should include human studies where appropriate.

Reliability of evidence denotes it has to be

- consistent in itself,
- able to meet accepted scientific standards of statistical and biological significance,
- plausible in terms of the relationship between intervention and results and
- provided by several sources including human studies. The totality of the evidence should be systematically reviewed. Evidence can be derived from peer reviewed scientific literature, in vitro studies, animal models, clinical studies, epidemiological studies, or any other relevant studies.

The CIAA code refers to the results of the FUFOSSE program: The EU Concerted Action on Functional Food Science in Europe requires that claims be based on the establishment and acceptance of either validated markers of improved physiological function or of intermediate endpoint markers of reduced risk of disease.

Human studies must be carried out in a representative sample of the population or population group concerned in accordance with good clinical practice. The use of internationally accepted and validated methods and of biological markers is recommended when they exist. They should demonstrate efficacy with respect to the specific physiological effect(s). An effective level and frequency of consumption should be suggested for a food claiming to have a positive effect on health. The effect must be studied over sufficient time to allow adaptation to occur and should consider confounding factors such as health status at the time of the study, use of medication and/or smoking.

The effect must be quantitatively, statistically and biologically *significant*. The measured effect must be shown to be sufficiently important to justify the claim. If the composition or manufacturing processes change substantially, or if new scientific developments occur, additional checks must be carried out to ensure the continued validity of the claim. It must be shown that the specific functional substance(s) is (are) present in the quantity and form needed to justify the claim throughout shelf life when stored under the conditions indicated

on the label. A normal or recommended serving size, conditions of use and consumption pattern should be incorporated into an assessment of the relevance of the concerned food with a nutritional intake of the population. Companies are encouraged to have their scientific evidence peer-reviewed.

The main European *Consumer* Association, Bureau European Union de Consommateurs (BEUC), was basically against health claims. In its view a single food product is neither healthy nor unhealthy. In contrast, only the diet can be healthy or unhealthy. They said all claims must be presented in the context of a balanced healthy diet. Claims should not be permitted on products that contradict well-established dietary advice, e.g. which contain high quantities of fat, sugar or salt.¹¹¹⁴ The requirements for scientific documentation and labelling requirements were more or less the same as in Council of Europe and CIAA guidelines.

For years, plans to introduce provisions into Community law to govern health claims existed. The Commission's directorate general for health and consumer protection ordered a study from consultancy firm Hill & Knowlton in the 90's. Their task was to study the legal situation in Member States relating to nutritional claims, health claims and ethical claims. Also, opinions of different interest groups were studied and based on their finding the consultants gave recommendations. The study was performed in the first half of 1999, and the results were given to the Commission in April 2000.

According to the Hill & Knowlton study, *consumer* groups acknowledged the need for health claims, and called for strict legislation to cover:

- pre-clearance of all claims,
- precise substantiation criteria to allow claims to be used (not positive or negative lists),
- reinforced post verification systems,
- better consumer information about the relationship between diet and health, and
- a shift in the burden of proof onto the maker of the claim.¹¹¹⁵

The *food industry* opinions were the following:

- EC rules are needed regarding health claims.
- New types of health claims should be allowed, and the Food Labelling Directive should be changed to allow this.
- Clear criteria for presenting health claims are needed
- There should be no system for pre-market approval, but well-defined post clearance verifications are in order.¹¹¹⁶

Food producers considered it a problem that different countries interpret the Food Labelling Directive and its prohibition of medicinal claims differently. This is the usual reason for harmonising an area of law: varying legislation creates restrictions to trade.

Majority of *official parties and legislators* were of the following view:

¹¹¹⁴ BEUC guidelines 2000, 4-7.

¹¹¹⁵ Hill & Knowlton 2000, 11.

¹¹¹⁶ Hill & Knowlton 2000, 12.

- EC rules regarding health claims are needed, and the Food Labelling Directive should be changed to allow new types of health claims.
- The work in Codex could form the basis of allowing new types of claims.
- The definition of food should be clearer so that drawing the line to medicinal products would be less complicated.
- For generic claims, a positive list could be made up. Pre-market approval for product-specific claims might be reasonable.¹¹¹⁷
- Voluntary codes can work as a temporary solution while waiting for the EC rules on health claims.¹¹¹⁸

Based on opinions of these three important interest groups (consumers, industry and governments) Hill and Knowlton proposed the following:

- To protect consumers, health claims should be regulated clearly at EC level.
- The Food Labelling Directive should be changed so that it would literally allow enhanced function claims and disease risk reduction claims.
- A list on general permissible claims should be created, and a notification procedure for so called new claims.
- The Nutrition Labelling Directive (Directive 90/464/EC) should be changed to comply with Codex guidelines on nutrition claims.
- The Misleading Advertising Directive (Directive 84/450/EC) should be changed to cover the control mechanisms for claims.
- The definition of food should be clarified.¹¹¹⁹
- A campaign to educate consumers on the connection between nutrition and health should be arranged.

After the Hill & Knowlton report, the Commission¹¹²⁰ continued to prepare new legislation on claims and published a discussion paper on *nutritional and functional claims* in 2001. The discussion paper was based on the idea that harmonisation is needed because of all the different rules restricting trade. The discussion paper presented different alternatives for defining ‘claim’, requirements for presenting a claim and for systems of assessment and acceptance of claims.

On nutrition claims, the paper suggested banning claims relating to dietary cholesterol¹¹²¹, considered the possibility to require some kind of nutritional profile of “low fat” foods, and presented suggestions on definitions of “low fat”, “sugar free” etc. For the so-called functional

¹¹¹⁷ Here generic seems to mean established, where product-specific means innovative.

¹¹¹⁸ Hill & Knowlton 2000, 12.

¹¹¹⁹ Since the study, food has been defined in the General Food Regulation, but all that definition says is that foods that are medicines are not foods.

¹¹²⁰ The Directorate General on Health and Consumer Protection, DG SANCO.

¹¹²¹ This is because dietary cholesterol is not a major factor in coronary heart disease and there is a danger of confusion with blood cholesterol levels. Consumers do not seem to understand the difference between dietary and blood cholesterol. High blood cholesterol is usually related to a diet rich in saturated fats.

claims, the paper suggested giving first the presence of the nutrient and then its role in human physiology, for example: “High on protein. Protein helps build and repair body tissues.”¹¹²²

The paper stated that claims must be substantiated with scientific evidence and that evidence must be relevant to consumers in terms of the final product they eat. The paper suggested a pre-market authorisation for nutritional and functional claims, and a list of acceptable and agreed claims for each nutrient or substance, including specific wording.¹¹²³

There were over 880 responses to the DG SANCO paper and it was hard to see how the different positions could be resolved and a consensus for a proposal reached.¹¹²⁴ For example, Italy was of the view that food claims “cater solely for commercial interests.” They thought the novel foods trend is dangerous and spoils all the food traditions. They warned that subsequent studies often revise the virtues of specific foods, no attention is paid to over consumption, and that a combined consumption of enriched products can cause problems. The UK, on the contrary, saw claims as enabling consumers to make healthy diet choices.

Besides nutritional and functional claims, the UK wanted health claims, and disease reduction claims, to be debated. Also, many other Member States, the food industry (particularly CIAA), and consumer groups commented on the absence of health claims from the first paper. They were in all probability left out, as they were considered even more difficult, as viewpoints on health claims vary from not wanting health claims at all, to those which would accept some claims under certain rules, to those that have a much more liberal policy.¹¹²⁵

There was a large amount of pressure on the Commission: several stakeholders *demand*ed legislation governing health claims. No one wanted to live in a non-harmonised state. This implies that legislation was considered necessary. The UK continued to allow a reduction of risk claims, and this resulted in conflict with the Commission, as Commission officials said these were illegal.¹¹²⁶ The Commission promised to prepare a Proposal for a Regulation on nutrition, functional *and* health claims. They planned that the Commission might adopt the proposal in early 2003. The Commission thus decided to put food claims together and abandoned the idea of separate discussion paper and proposal for health claims.¹¹²⁷

While waiting for the Commission proposal, a system where a list of claims was authorised, based on established scientific evidence, seemed attractive to both consumers and industry. This kind of blanket approval provides certainty and does not involve a lengthy approval procedure.¹¹²⁸ There seemed to be a fair amount of consensus on scientific substantiation of claims, and the importance of the total diet. Hill & Knowlton also proposed a notification procedure for novel claims, which was something the industry opposed but the consumers applauded.

In July 2003, the Commission adopted a *proposal* for a Regulation on the use of nutrition and health claims made on foods¹¹²⁹. According to the Commission, “the main objectives of the Commission’s proposal are to achieve a *high level of consumer protection* and increase

¹¹²² Other examples established by Codex: “Calcium aids in the development of strong bones and teeth”; “Iron is a factor in red blood cell formation” and “Vitamin E protects the fat in body tissues from oxidation”.

¹¹²³ Discussion paper on nutrition and functional claims, 10.

¹¹²⁴ EU Food Law November 2001, 7.

¹¹²⁵ EU Food Law November 2001, 7.

¹¹²⁶ EU Food Law June 2001, 10.

¹¹²⁷ European Commission’s Food Safety web page July 10, 2002.

¹¹²⁸ EU Food Law August 2001, 13.

¹¹²⁹ COM(2003) 424 final. Brussels, 16.7.2003.

legal security for economic operators. It also aims to ensure *fair competition* and *promote and protect innovation* in the area of food. By adopting rules on the information given about foods and the nutritional values appearing on labels, the Commission was aiming to ensure that consumers would be able to make *informed and meaningful choices* when it came to food and drinks. The health and nutrition claims rules will also contribute to a *higher level of human health protection*, as it ties in with the Commission's campaign for healthier lifestyle choices by allowing citizens to know exactly what they are consuming.¹¹³⁰ The Commission tried to respond to all the demands presented: particularly consumers wanting more reliable information and the industry wanting clear and harmonised rules not discouraging innovation.

The European Parliament held its first reading vote on the Commission's proposal in May 2005.¹¹³¹ The parliament tried to delete both the article on the authorisation procedure and the article on nutrition profiles. The Internal Market Committee of the European Parliament voted to delete the articles in April 2005. On the authorisation procedure, the vote was 20 for deletion and 14 against. The result of the vote on nutrition profiles was 19 for deletion and 14 against. With both Articles, the EPP (Christian-Democrats) and ALDE (Liberals) voted for deletion, and the PES (Socialists) and Greens voted against deletion.¹¹³² The Commission did not accept the deletions and gave another proposal including the contested articles.

In June 2005, EU health ministers unanimously endorsed the Commission's proposal, including the provision for nutrient profiles and the authorisation procedure, during a first reading vote at the Health Council. The European Parliament second reading vote took place in May 2006.¹¹³³ Formal adoption of the Regulation by the Parliament and the Council occurred in December 2006. Regulation 1924/2006/EC¹¹³⁴ entered into force in January 2007, and became applicable in the beginning of July 2007. This means that after all the years of discussion and preparation, the EU finally has a regulation on nutrition and health claims. The Regulation is analysed in detail below.

5.3.3.2 General Requirements on Claims

Regulation 1924/2006/EC applies to nutrition and health claims made in *commercial communications*, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer. It also applies in respect of foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.¹¹³⁵ Nutrition and health claims may be used on foods placed on the market in the European Community only if they comply with the provisions of the Regulation.

Article 3 lists "the general principles for all claims". The use of nutrition and health claims shall not:

¹¹³⁰ European Commission's Food Safety web page September 21st 2006.

¹¹³¹ European Commission web page at: http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm.

¹¹³² Foodnavigator news 20 April 2005. <http://www.foodnavigator.com/news/ng.asp?n=59508-imco-votes-to>.

¹¹³³ European Commission web page at: http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm.

¹¹³⁴ Regulation 1924/2006/EC of the European Parliament and of the Council, of 20 December 2006, on nutrition and health claims made on foods.

¹¹³⁵ Article 1(2).

- (a) be false, ambiguous or misleading;
- (b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;
- (c) encourage or condone excess consumption of a food;
- (d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general¹¹³⁶;
- (e) refer to changes in bodily functions that could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.

Article 5 lists “the general conditions” for claim use. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

- (a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made *has been shown to have a beneficial nutritional or physiological effect*, as established by generally accepted scientific evidence;
- (b) the nutrient or other substance for which the claim is made:
 - (i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or
 - (ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;
- (c) where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;
- (d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;
- (e) compliance with the specific conditions set out in Chapter III Nutrition Claims or Chapter IV Health Claims as the case may be.

The use of nutrition and health claims shall only be permitted if the average consumer¹¹³⁷ can be expected to understand the beneficial effects as expressed in the claim. Nutrition and health

¹¹³⁶ There are nutrients, for which sufficient quantities cannot be provided by a balanced and varied diet. Derogations for these cases, including the conditions for their application, may be adopted in accordance with the procedure referred to in Article 25(2), taking into account the special conditions present in Member States.

¹¹³⁷ According to preamble 16 of the Regulation, the average consumer test is not a statistical test.: “National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.” The average consumer means a person, who is reasonably well-informed and reasonably observant and circumspect. If a claim is specifically aimed at children, the claim should be assessed from the perspective of an average child.

claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions.

Article 6 concerns *scientific substantiation of claims*: Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence. A food business operator making a nutrition or health claim shall justify the use of the claim. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation.

Article 7 clarifies the rule on *mandatory nutrition information*. As described above¹¹³⁸, Directive 90/496/EEC has previously required nutrition information to be given in cases where a nutrition claim is made. The same rule applies to health claims. With health claims, the information to be provided shall consist of information in *Group 2* as defined in Article 4(1) of Directive 90/496/EEC. In addition and as the case may be, the amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall also be stated in the same field of vision as the nutrition information and be expressed in accordance with Article 6 of Directive 90/496/EEC.¹¹³⁹

Claims on alcoholic drinks are restricted¹¹⁴⁰. Later the Commission may determine other foods or food categories, for which nutrition or health claims are to be restricted or prohibited. This shall be done in the light of scientific evidence.¹¹⁴¹

The Commission, more particularly its Scientific Committee on Food Safety and Animal Health gave a guidance document¹¹⁴² where the relationship between the Regulation and other Community law is clarified in December 2007. On dietetic foods, it is stated that they can bear claims authorised on the basis of Regulation 1924/2006/EC. However, this does not apply to infant formula: the only permitted claims on these products are listed in Annex IV of Directive 2006/141/EC.¹¹⁴³

5.3.3.3 Nutrient Profiles

5.3.3.3.1 The Nutrient Profile as a Condition for Claim Use

The new regulation includes the principle that the use of claims is conditional on respecting *the overall nutrient profile of the food*. This means perhaps the most controversial thing about the new regulation that only “good foods” are allowed to have claims. The application of nutrient profiles as a criterion for nutrition and health claims aims to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product. Nutrient profiles should be based on generally accepted scientific evidence on

¹¹³⁸ Chapter 5.2.1.3.

¹¹³⁹ In the case of food supplements, the nutrition information shall be provided in accordance with Article 8 of Directive 2002/46/EC.

¹¹⁴⁰ Only nutrition claims referring to low alcohol levels or low energy levels are allowed. Health claims on alcohols are prohibited. Article 4(3).

¹¹⁴¹ Regulation 1924/2006/EC, Article 4(5).

¹¹⁴² Guidance on the Implementation of Regulation N° 1924/2006 on Nutrition and Health Claims Made on Foods. Conclusions of the Standing Committee on the Food Chain and Animal Health. 14 December 2007.

¹¹⁴³ Scientific Committee Claim Guidance 2007, 4.

the relationship between diet and health. At the same time, profiles should also allow for product innovation, and take into account various dietary habits and traditions.¹¹⁴⁴

Nutrient profiles will be based on the content of different nutrients and substances with a nutritional or physiological effect. This means calculating the amounts of fat, saturated fat, trans-fatty acids, poly- and mono-unsaturated fats, salt/sodium, sugars, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. Some of these nutrients and substances are avoidable; some are beneficial. It is not merely the nutritional content that resolves the issue of claims. When setting the nutrient profiles, the different categories of foods and *the place and role of these foods in the overall diet* should be taken into account. Due regard should be given to the various dietary habits and consumption patterns existing in the Member States.¹¹⁴⁵

EFSA has given its scientific opinion on nutrient profiles in January 2008 and has consulted stakeholders. Scientists and governments have developed different nutrition profiling models. The Commission was to establish nutrient profiles for different foods and food categories by 19 January 2009. This work has been delayed. With the nutrient profiles, the Commission shall establish all the conditions for the use of claims and also the exemptions. The nutrient profiles for food and/or certain categories of food shall be established taking into account in particular:

- (a) the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium;
- (b) the role and importance of the food (or of categories of food) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children;
- (c) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.¹¹⁴⁶

The nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health. In setting the nutrient profiles, the Commission shall request EFSA to provide scientific advice, focusing in particular on:

- whether profiles should be set for food in general and/or categories of food;
- the choice and balance of nutrients to be taken into account;
- the choice of reference quantity/basis for profiles;
- the approach to the calculation of the profiles; and
- the feasibility and testing of a proposed system.¹¹⁴⁷

After setting up the profiles, the Commission shall continue to carry out consultations with interested parties, in particular food business operators and consumer groups. Nutrient profiles and their conditions of use shall be updated to take into account relevant scientific

¹¹⁴⁴ Regulation 1924/2006/EC, preamble 11.

¹¹⁴⁵ Regulation 1924/2006/EC, preamble 12.

¹¹⁴⁶ Regulation 1924/2006/EC, Article 4(1).

¹¹⁴⁷ Regulation 1924/2006/EC, Article 4(1).

developments, after consultation with interested parties, in particular food business operators and consumer groups.¹¹⁴⁸

It is not yet clear how many different nutrition profiles will be created. According to a DG Sanco representative, a single set of profiles may be too rigid but on the other hand, an excessive number of food categories could be rather unmanageable. A solution might lie in combining an overall nutrient profile with derogations, adjustments and exemptions for a limited number of categories of foods or individual foods. These could be identified by taking account of Article 4(1): “(b) the role and importance of the food [...] and the contribution to the diet [...] (c) [...] the presence of nutrients that have been scientifically recognised as having an effect on health.”¹¹⁴⁹

According to a German government agency, there is no need to elaborate nutrient profiles for food categories that only include primary agricultural products (e.g. fish, meat, fruit or vegetables)¹¹⁵⁰. The Commission seems to share this view, as a Commission representative suggests setting profiles for the following food categories:

- 1) Vegetable oils
- 2) Spreadable fats
- 3) Dairy products
- 4) Cereal products (bread, breakfast cereals)
- 5) Fruit products
- 6) Other foods¹¹⁵¹.

It might be necessary to set up separate categories also for ready meals (including soups, pizza etc.), beverages (non-alcoholic), and desserts, snacks and sweets.¹¹⁵²

Nutrient profiles include several difficult questions: The balance of nutrients in the whole diet must be taken into account. A beneficial nutrient such as calcium or fibre might balance the effect of a fat or a sugar. There is a lack in uniformity regarding portion sizes, and diets vary among European food cultures. Grouping nutrients as ‘good’ or ‘bad’ is too straightforward.

¹¹⁴⁸ Regulation 1924/2006/EC, Article 4(1).

¹¹⁴⁹ Didion 2007.

¹¹⁵⁰ Bundesinstitut für Risikobewertung: Nutrient Profiles. The Precondition for Health Claims. Updated Position Paper 12 March 2007.

¹¹⁵¹ Didion 2007.

¹¹⁵² The Finnish “Report on health claims used in marketing of foodstuffs in Finland”, page 22, classifies food products into the following 12 categories:

- 1) Milk and milk products
- 2) Cheese and cheese-like products
- 3) Meat, poultry, eggs, charcuterie products
- 4) Fish and fish products
- 5) Cereal products
- 6) Vegetables, fruits and berries
- 7) Ready meals
- 8) Vegetable oils
- 9) Spreadable oils
- 10) Beverages
- 11) Desserts, snacks and sweets
- 12) Others.

For example all trans-fatty acids are not harmful. *The nutrient profiles established by the Commission will undoubtedly be controversial and raise criticism.* Nutrient profiles and their conditions of use shall be updated to take into account relevant scientific developments in accordance with the Committee procedure and after consultation of interested parties, in particular food business operators and consumer groups¹¹⁵³.

Previously, claims have been allowed if they are true. Now the food must additionally be *healthy as a whole*. Evaluating the food as a whole takes the prohibition of misleading advertising to a new level. Now the consumer does not have to weigh the benefit of the claim to some unhealthy features of the food. Conversely, the consumer cannot use health claims as guidance on which *unhealthy* product to choose. The nutrient profile approach is more paternalistic than the previous system, but is justified because of the difficulties in evaluating the issues of nutrition.

In making up the profiles, some products will end up being ‘bad’ in a sense that nothing good can be said about them. The prohibition to make claims might sound unfair to producers of various products, such as producers of functional confectionary. It seems that *public health concerns outweigh freedom of speech*. Unhealthy food producers are becoming legally equated with tobacco and alcohol producers. Tobacco and alcohol are legal products. Still, marketers have very limited space: there are restrictions, limitations, and obligations. Tobacco and alcohol companies have no real right to freely sell their products, which is no longer questioned.

5.3.3.3.2 The Derogation

By way of derogation from the rule described above, *nutrition claims* (it is important to notice that the exception does not apply to health claims):

- “(a)referring to *the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium* shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, ...
- (b) shall be allowed, where *a single nutrient* exceeds the nutrient profile provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This statement shall read as follows: “High [the name of the nutrient exceeding the nutrient profile] content”¹¹⁵⁴.

Point (a) means that one can claim ‘reduced amount of harmful nutrient’ even if the product does not fit the profile.

Point (b) is more controversial. It means that if a nutrient profile, for example, includes limits for fat, salt, and sugar, and the product exceeds one of the three limits, it can still bear nutrition claims, for example, “low-fat” or “high in fibre”.

Prior to Parliament’s second reading vote in May 2006, “a slight amendment to Article 4 was agreed between Council and Parliament, whereby a nutrition claim will still be permitted if only *one nutrient* (e.g. salt, sugar or fat) exceeds the limit of the nutritional profile”¹¹⁵⁵. This

¹¹⁵³ Regulation 1924/2006/EC, Article 4(1).

¹¹⁵⁴ Regulation 1924/2006/EC, Article 4(2).

¹¹⁵⁵ European Commission Press release IP/06/625, 16/05/2006.

“slight amendment” is a political compromise and the requirement for a healthy nutritional profile is not fully realised. The preambles of the Regulation do not explain the derogation. The derogation would sound strange to a nutritional scientist, as it seems to dilute the whole idea of only healthy products having claims. Why draw up a nutritional profile, if the product does not have to fit that profile? The amendment saved a lot of products: for instance, a ready-made meal that has a lot of saturated fats but no salt or sugar might be able to bear claims relating to the low amounts of salt and sugar. Of course, the derogation was created precisely for this reason: to allow important product groups to derogate. *For a scientist, legislation creates artificial boundaries. For a politician, legislation creates necessary compromises.*

The derogation led to the need to indicate the remaining unhealthy ingredient. According to the agreed rule, *the high level of the substance exceeding the nutritional profile limit must be clearly marked* on the label, close to and with the same prominence as the claim. This leads to unclear messages on labels, for example, a product might have a claim “low fat” next to the text “high in sugar”. How will a consumer react? After reading the regulation carefully, he would be able to determine that the product is high in sugar but low in fat and also low in other harmful nutrients. But the consumer will not be able to determine whether the excess amount of sugar makes the product unhealthy as a whole.

In practice, the derogation creates a situation where there are in practice *alternative nutritional profiles* which the product must fulfill. These alternatives are certainly not equivalent according to nutritional science. For example, popcorn with salt and popcorn with sugar are not equivalent although they both have one ingredient that is not healthy. On the other hand, this simplistic and unscientific thinking is close to the procedures that a consumer may consider: “today I avoid sugar, tomorrow I avoid salt”. The consumer does not know exactly how each dietary change effects her health, but she might want to take steps in the right direction by purchasing a product that “does something right”.

Concerning nutrition claims, the message given to the food industry is that as long as they put something good in the food products, products are OK. It would have been a lot stricter - and clearer - if they had to make the products healthy as a whole before they could attach any nutrition claims to them.

5.3.3.4 Nutrition Claims

According to European definition, “nutrition claim” means any claim, which *states, suggests or implies* that a food has *particular beneficial nutritional properties* due to:

- (a) the energy (caloric value) it
 - (i) provides;
 - (ii) provides at a reduced or increased rate; or
 - (iii) does not provide; and/or
- (b) the nutrients or other substances it
 - (i) contains;
 - (ii) contains in reduced or increased proportions; or
 - (iii) does not contain¹¹⁵⁶.

¹¹⁵⁶ Regulation 1924/2006/EC, Article 2(2)(4).

The new Regulation 1924/2006/EC lays down strict conditions for the use of nutritional claims such as “low fat”, “high fibre” or “reduced sugar”. Nutrition claims shall only be permitted if they are listed in the Annex and are in conformity with the conditions set out in the Regulation. Amendments to the Annex shall be adopted in accordance with the committee procedure and, where appropriate, after consulting the EFSA.¹¹⁵⁷

The following nutrition claims and the conditions for their use are listed in the Annex:

- “low calorie”¹¹⁵⁸,
- “reduced calorie”¹¹⁵⁹,
- “calorie-free”¹¹⁶⁰,
- “low fat”¹¹⁶¹,
- “fat-free”¹¹⁶²,
- “low saturated fat”¹¹⁶³,
- “saturated fat-free”¹¹⁶⁴,
- “low sugars”¹¹⁶⁵,
- “sugar-free”¹¹⁶⁶,

¹¹⁵⁷ Regulation 1924/2006/EC, Article 8.

¹¹⁵⁸ “A claim that a food is low in calorie, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.”

¹¹⁵⁹ A claim that a food is reduced-calorie, and any claim likely to have the same meaning for the consumer, may only be made where the caloric value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total caloric value.

¹¹⁶⁰ A claim that a food is calorie free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0.4 kcal (1.7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.

¹¹⁶¹ A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100 ml for liquids (1.8 g of fat per 100 ml for semi-skimmed milk).

¹¹⁶² A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5 g of fat per 100 g or 100 ml. However, claims expressed as “X % fat-free” shall be prohibited.

¹¹⁶³ A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1.5 g per 100 g for solids or 0.75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.

¹¹⁶⁴ A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the sum of saturated fat and trans-fatty acids does not exceed 0.1 g of saturated fat per 100 g or 100 ml.

¹¹⁶⁵ A claim that a food is low in sugars, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5 g of sugars per 100 g for solids or 2.5 g of sugars per 100 ml for liquids.

¹¹⁶⁶ A claim that a food is sugar-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5 g of sugars per 100 g or 100 ml.

- “with no added sugars”¹¹⁶⁷,
- “low sodium/salt”¹¹⁶⁸,
- “very low sodium/salt”¹¹⁶⁹,
- “sodium-free or salt-free”¹¹⁷⁰,
- “source of fibre”¹¹⁷¹,
- “high fibre”¹¹⁷²,
- “source of protein”¹¹⁷³,
- “high protein”¹¹⁷⁴,
- “source of [name of vitamin/s] and/or [name of mineral/s]”¹¹⁷⁵,
- “high [name of vitamin/s] and/or [name of minerals]”¹¹⁷⁶,
- “contains [name of the nutrient or other substance]”¹¹⁷⁷,

¹¹⁶⁷ A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: “CONTAINS NATURALLY OCCURRING SUGARS”.

¹¹⁶⁸ A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.

¹¹⁶⁹ A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters.

¹¹⁷⁰ A claim that a food is sodium-free or salt-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.005 g of sodium, or the equivalent value for salt, per 100 g.

¹¹⁷¹ A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3 g of fibre per 100 g or at least 1.5 g of fibre per 100 kcal.

¹¹⁷² A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.

¹¹⁷³ A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12% of the energy value of the food is provided by protein.

¹¹⁷⁴ A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20% of the energy value of the food is provided by protein.

¹¹⁷⁵ A claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

¹¹⁷⁶ A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of “source of [name of vitamin/s] and/or [name of mineral/s]”.

¹¹⁷⁷ A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular Article 5. This means there must be sufficient quantities of the nutrient present to make a beneficial effect. For vitamins and minerals the conditions of the claim “source of” shall apply.

- “increased [name of the nutrient]”¹¹⁷⁸,
- “reduced [name of the nutrient]”¹¹⁷⁹,
- “light/lite”¹¹⁸⁰,
- “naturally/natural”¹¹⁸¹.

The claim “as much as” is not in the Annex of the Regulation and is consequently not allowed. Neither is the claim “super light”.¹¹⁸²

The *comparative nutrition claims* listed in the annex are the following: “increased [name of the nutrient]”, “reduced [name of the nutrient]”, “reduce calorie” and “light”. With regard to comparative nutrition claims, a comparison may only be made between foods of the *same category*, taking into consideration a *range of foods* of that category¹¹⁸³. The food shall be compared to foods that do not have a composition, which allows them to bear a claim, including foods of other brands. The difference in the quantity of a nutrient and/or the energy value shall be stated, and the comparison shall relate to the same quantity of food.¹¹⁸⁴

The Scientific Committee on Food Safety and Animal Health has in its Guidance Document of December 2007 defined more precise rules for comparative nutrition claims. “Same category” means that products are *similar in terms of nutritional content*¹¹⁸⁵. “Dairy products” is too wide a category as milk and cheese cannot be compared but “Milks” can be compared with other milks, and “cheeses” with other cheeses.¹¹⁸⁶

It should be noted that *the claim “contains” could also be interpreted as a health claim*. The Committee Guidance states that while the claim “contains” is normally a nutrition claim, in some cases the use of the term “contains” refers to “groups of substances with a specific functional effect”. In such cases, the “contains” claim is a health claim and must be authorised accordingly.¹¹⁸⁷ Regardless of whether “contains” claims are judged as nutrition claims or health claims, the general requirements on claims apply. This means that the substance subject to the claim is present in a significant quantity and has been shown to have a beneficial

¹¹⁷⁸ A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim “source of” and the increase in content is at least 30% compared to a similar product.

¹¹⁷⁹ A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30% compared to a similar product, except for micronutrients, where a 10% difference in the reference values as set in Directive 90/496/EEC shall be acceptable, and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.

¹¹⁸⁰ A claim stating that a product is “light” or “lite”, and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term “reduced”; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food “light” or “lite”.

¹¹⁸¹ Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term “naturally/natural” may be used as a prefix to the claim.

¹¹⁸² This guidance for given in the December 2007 Guidance by the Scientific Committee on Food Health and Animal Health, page 7.

¹¹⁸³ This means the marketer cannot choose a suitable product against which to make the comparison.

¹¹⁸⁴ Regulation 1924/2006 EC, Article 9.

¹¹⁸⁵ Scientific Committee Claim Guidance 2007, 7.

¹¹⁸⁶ Scientific Committee Claim Guidance 2007, 8.

¹¹⁸⁷ Scientific Committee Claim Guidance 2007, 11.

nutritional or physiological effect. One also has to keep in mind that the use of any claim triggers the nutrition labelling requirement discussed above in chapter 5.2.1.3.¹¹⁸⁸

The Guidance gives examples of “contains” claims that are interpreted as nutrition claims and “contains” claims that are interpreted as health claims. A claim is a nutrition claim if in the naming of the substance or category of substances, there is only factual information, for example: “contains lycopene”, and “contains lutein”.¹¹⁸⁹

A claim is a health claim if in the naming of the substance or category of substances, there is *a description or indication of functionality or an implied effect on health*. For example “contains antioxidants” will be interpreted as a health claim, because the function is an antioxidant effect. “Contains probiotics/prebiotics” will be interpreted as a health claim, because the reference to probiotic/prebiotic implies a health benefit. “With prebiotic fibres” or “contains prebiotic fibres” will be interpreted as health claims, because by using an adjective, they *describe* a nutrient or a substance and thus refer to functionality.¹¹⁹⁰

The distinction between a nutrition claim and a health claim does not seem clear after all. It is difficult to separate between substances the mentioning of which does not imply any function, and the mentioning of which does. After all, many nutrients and substances have necessary and thus beneficial functions in the body, and the advances in nutritional science keep providing us with more and more information on these diet-health connections. This might lead to a situation where mentioning any nutrient will be considered a health claim and the need for a legal concept such as ‘nutrition claim’ will cease to exist.

5.3.3.5 Health Claims

5.3.3.5.1 General Requirements for the Use of Health Claims

“*Health claim*” means any claim that *states, suggests or implies* that a relationship exists between a food category, a food or one of its constituents and health¹¹⁹¹. “*Reduction of disease risk claim*” is a subcategory of “health claim”. It means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents *significantly reduces a risk factor in the development of a human disease*¹¹⁹².

Health claims are prohibited unless they A) comply with the general requirements for claims (for example the nutrition profile), B) comply with the specific requirements for health claims, C) are authorised in accordance with the Regulation, and D) are included in the lists of authorised claims.¹¹⁹³ There are two authorisation routes and lists for claims. The list of established claims will be created according to Article 13, and a list of novel claims pursuant to Article 14. The authorisation procedures for including claims on the lists are stipulated by

¹¹⁸⁸ Scientific Committee Claim Guidance 2007, 11.

¹¹⁸⁹ Scientific Committee Claim Guidance 2007, 11.

¹¹⁹⁰ Scientific Committee Claim Guidance 2007, 11.

¹¹⁹¹ Regulation 1924/2006/EC, Article 2(2)(5).

¹¹⁹² Regulation 1924/2006/EC, Article 2(2)(6).

¹¹⁹³ Regulation 1924/2006/EC, Article 10(1).

Articles 15, 16, 17 and 18. These procedures will be discussed above in detail. Article 19 concerns modification, suspension and revocation of authorisations¹¹⁹⁴.

When using health claims, one must always provide the consumer with *additional information*. Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

- (a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
- (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- (c) where appropriate, a statement addressed to persons who should avoid using the food; and
- (d) an appropriate warning for products that are likely to present a health risk if consumed to excess.¹¹⁹⁵

It is prohibited to use health claims suggesting that health could be affected by not consuming the food¹¹⁹⁶. Reference to *general, non-specific benefits* of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the Community lists.¹¹⁹⁷

National rules on *recommendations of national associations* of medical, nutrition or dietetic professionals and health-related charities may apply in the absence of specific Community rules¹¹⁹⁸. It is prohibited to use claims making reference to other associations, and claims making reference to recommendations of individual doctors or health professionals¹¹⁹⁹.

There is also one particular claim type that is prohibited: *claims that make reference to the rate or amount of weight loss*¹²⁰⁰. Commission Directive 96/8/EC on dietetic foods for weight reduction had previously prohibited this type of claims. It was considered appropriate to extend this restriction to all foods. See chapter 5.2.1.4. on marketing of dietetic products.

Other controversial claim types such as psychological and behavioural claims were not prohibited but it was clearly stated that scientific substantiation is required to back up these

¹¹⁹⁴ The applicant or a user of a claim included in the lists may apply for a modification of the relevant list. The regular procedures for claim approval apply. Modification, suspension and revocation of authorised claims can be initiated by the EFSA, a Member State or the Commission. The EFSA shall issue an opinion on whether a health claim included in the lists still meets the conditions laid down in the Regulation. It shall transmit its opinion to the Commission, the Member States and, where relevant, to the original applicant of the claim in question. The Authority shall make its opinion public. The applicant/user or a member of the public may make comments to the Commission within 30 days of such publication. The Commission shall examine the opinion of the Authority and any comments received as soon as possible. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the Committee procedure.

¹¹⁹⁵ Regulation 1924/2006/EC, Article 10(2).

¹¹⁹⁶ Regulation 1924/2006/EC, Article 12(a).

¹¹⁹⁷ Regulation 1924/2006/EC, Article 10(3).

¹¹⁹⁸ Regulation 1924/2006/EC, Article 11.

¹¹⁹⁹ Regulation 1924/2006/EC, Article 12(c).

¹²⁰⁰ Regulation 1924/2006/EC, Article 12(b).

claims¹²⁰¹. This means for example that claims stating “refreshing”, “helps you concentrate”, “helps you sleep” cannot be used without fulfilling all the requirements for health claims. Claims related to children were also not prohibited. This was another controversial issue. Instead, claims were subject to a more stringent Article 14 procedure.

5.3.3.5.2 ‘Function’ Claims

Article 13 of the Regulation creates the authorisation procedure for health claims *other than those referring to the reduction of disease risk and to children’s development and health*. These are health claims describing or referring to:

- (a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- (b) psychological and behavioural functions; or
- (c) slimming *or* weight-control *or* a reduction in the sense of hunger *or* an increase in the sense of satiety *or* the reduction of the available energy from the diet¹²⁰².

The European scientific community has started to call these health claims “function” claims¹²⁰³. These claims are legal without product-specific authorisation, if they are on the Community list of established claims. Claims can only be included in the list if they are:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.¹²⁰⁴

These types of claims can be such as: ‘ingredient A of this product promotes bowel movement’, ‘compound B reinforces bones’, ‘raw material C refreshes’ and ‘raw material D of the product increases the sense of satiety and supports weight control’¹²⁰⁵.

The Commission shall adopt, in accordance with the Committee procedure, *a positive Community list of well-established claims by 31 January 2010 at the latest*.¹²⁰⁶ This list of permitted claims will include all the necessary conditions for the use of these claims. Before the adoption of the list by the Commission, the EFSA will evaluate the scientific evidence of the claims. The claims on the list may be used on a label as long as they are proven to apply to the food in question.

It is not an easy task to produce the list of established claims. By 31 January 2008, Member States had to submit to the Commission a list of claims approved at national level. This

¹²⁰¹ Regulation 1924/2006/EC, preamble 24. “There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods.”

¹²⁰² Without prejudice to Directive 96/8/EC.

¹²⁰³ See presentations at NHClaims Congress in Naantali, Finland 7 – 9 November 2007, <http://congress.utu.fi/NHC2007/presentations.php>.

¹²⁰⁴ Regulation 1924/2006/EC, Article 13(1).

¹²⁰⁵ Report on health claims used in marketing of foodstuffs in Finland. Page 4.

¹²⁰⁶ Regulation 1924/2006/EC, Article 13(3).

means claims that are based on generally accepted scientific evidence and well understood by consumers, and thus deemed acceptable by national authorities. The national list of claims shall be accompanied by the conditions applying to the claims and by reference to the relevant scientific justification.¹²⁰⁷ The Commission received similar proposals from all the 27 EU Member States by the beginning of 2008. This means the EFSA and the Commission will have 2 years, beginning in 2008 when the national reports arrive, to compile the EU list.

To predict what the Community list will look like, we now take a look at the contents of the Finnish list. The Food Safety Authority¹²⁰⁸ and the Ministry of Trade and Industry produced the Finnish list. Health claims are widely used in Finland, but previously there has not been a national list of accepted claims. The Authority collected information on health claims by using a questionnaire on its web page¹²⁰⁹. Disease risk reduction claims were not included; as they are a separate issue, see below. A total of 625 questionnaires were returned by the deadline. Preliminary results of the replies were presented and discussed in a seminar held in December 2006. The final report of the study was presented to the Finnish Ministry of Trade and Industry in January 2007. The Finnish proposal for acceptable claims and the relevant scientific justification will be sent to the Commission by the Ministry of Trade and Industry at the beginning of 2008.¹²¹⁰

The Finnish report, a 316-page document of applicable health claims¹²¹¹ is based on the information received from entrepreneurs, and includes numerous scientific references. Based on this data, the Finnish authorities prepared their list and sent it to the Commission. If we look at the Finnish report, we can understand the challenge faced by the EFSA and the Commission. We can also find out the most popular claims and the products that typically generate these claims.

Consequently, half of the foodstuffs declared were food supplements and about half were conventional foodstuffs¹²¹². This means that from a marketing point of view, health claims are equally important to functional food and food supplement businesses. There were altogether 269 substances or combinations of substances, pertaining to which claims were presented¹²¹³.

Of the different categories of Article 13 claims, claims describing the role of a nutrient in growth, development and/or the functions of the body represented 88% of the claims. Psychological and behavioural claims made up 5% and weight-loss claims 7% of the total. The last group includes

¹²⁰⁷ Regulation 1924/2006/EC, Article 13(2).

¹²⁰⁸ In Finnish: Elintarviketurvallisuusvirasto, Evira.

¹²⁰⁹ The internet questionnaire was on the Evira web page from March 2006 until August 2006, and again in October 2006 because of several inquiries.

¹²¹⁰ Food Safety Agency web page at: http://www.evira.fi/portal/en/food/current_issues/?id=349.

¹²¹¹ Information on what types of product are used in the claims, and on the scientific justification on which the claims are based according to the respondents, can be found in the detailed Finnish report (Vaihia K. - Sarlio-Lähteenkorva S.: Selvitys Suomen elintarvikemarkkinoilla käytettävistä terveystähteistä. Eviran julkaisuja 8/2007, 316 pages, available at: http://www.palvelu.fi/evi/files/55_519_486.pdf. Report on health claims used in marketing of foodstuffs in Finland. (English summary, 146 pages) available at: http://www.palvelu.fi/evi/files/55_519_492.pdf.

¹²¹² Report on health claims used in marketing of foodstuffs in Finland, 10.

¹²¹³ We need to remember that this figure includes only health claims that are not related to reduction of disease risk or children's development. Nutrition claims and medicinal claims are naturally also excluded from this figure.

claims that relate to slimming, weight control, a reduction in the sense of hunger, an increase in the sense of satiety, or a reduction of the available energy from the diet.¹²¹⁴

The claims are typically used at least in labelling and advertising. Health claims were used on labels in 96% of the cases, and in brochures or advertising in 99.7% of the cases. Claims are also frequently used in expert material (86% of the cases), and also with other marketing channels such as fairs or product presentations (54%).¹²¹⁵

Health claims were made in relation to a total of 269 different compounds, foodstuffs and ingredient combinations. Almost every product had some kind of scientific evidence to back up the claim. Only 4 of 625 claims were not based on any kind of science. The scientific evidence backing the claims varied in type. Evidence ranged from clinical trials of the product itself (22%) to clinical trials of a corresponding product (53%) to research of the ingredient (65%). Half of the claims were also backed up by general textbook information.¹²¹⁶ All in all, the Finnish claims seem to have a fairly sound scientific basis. This information could predict that most of the Finnish claims will be accepted and established by the Community list.

The Finnish claims were classified using the PASSCLAIM project classification¹²¹⁷. However, there were also claims, which did not fit into any of the Passclaim categories. The Passclaim categories are the following:

1. Diet-related cardiovascular disease
2. Bone health and osteoporosis
3. Physical performance and fitness
4. Body weight regulation, insulin sensitivity and diabetes risk
5. Diet-related cancer
6. Mental state and performance
7. Gut health and immunity.¹²¹⁸

The greatest number of claims was related to cardiovascular health, especially to cholesterol and blood pressure. There were also claims on other fat values in the blood, the circulation, the vascular system and blood clotting, homocysteine metabolism, as well as general cardiovascular health. For example, cholesterol control claims are used on pectin in natural berries, and cholesterol reduction claims on blackcurrant seed oil combined with vitamin E, soluble plant and berry fibre, and linolenic acid in sea buckthorn berries.¹²¹⁹ Blood pressure claims were made on sodium in natural berries¹²²⁰. General cardiovascular claims were made on sea buckthorn berry oil, hawthorn, and blackcurrant seed oil combined with vitamin E¹²²¹.

¹²¹⁴ Report on health claims used in marketing of foodstuffs in Finland 2007, 10.

¹²¹⁵ Report on health claims used in marketing of foodstuffs in Finland 2007, 10.

¹²¹⁶ Report on health claims used in marketing of foodstuffs in Finland 2007, 10.

¹²¹⁷ PASSCLAIM was a European Commission Concerted Action Programme in the years 2001-2005 carried out by the International Life Science Institute (ILSI) Europe. The final reports of the project are available at Passclaim website <http://europe.ilsa.org/activities/ecprojects/PASSCLAIM/>.

¹²¹⁸ Report on health claims used in marketing of foodstuffs in Finland, page 10.

¹²¹⁹ There are basically two types of cholesterol claims: claims which refer to the control of cholesterol and claims which refer to the reduction of cholesterol or the LDL/HDL ratio. Report on health claims used in marketing of foodstuffs in Finland 2007, 11-12.

¹²²⁰ Report on health claims used in marketing of foodstuffs in Finland 2007, 13.

¹²²¹ Report on health claims used in marketing of foodstuffs in Finland 2007, 13-14.

Many claims were also linked to carbohydrate metabolism and weight control, gut health and immunity, and general immunity. Claims on carbohydrate metabolism and/or insulin sensitivity were made for example on soluble plant and berry fibre. Gut health claims were made on sea buckthorn berry oil, fruit and berry juice fibre, and natural berry fibre.¹²²² Claims on general immunity were made on blackcurrant seed oil and sea buckthorn berry oil¹²²³.

Other important claim categories were claims related to the musculoskeletal system and mental health, and claims related to antioxidation. Other claims were on physical performance, oral and dental health, skin, hair and nail health, and eye health. Claims related to *antioxidation* were presented as only one factor among other principal claims. For example, a claim linked to cardiovascular health may be made, and in addition it is stated that the substance in question is also an antioxidant. Antioxidant claims were made on berry and fruit juices, berry seed oils, bilberry, forest bilberry, cranberry extract, flavonoids extracted from sea buckthorn oil and sea buckthorn berry, and phenolic compounds of cranberry and lingonberry.¹²²⁴

When deciding the claims to be put on the list of established claims, the most important question is *the level of scientific evidence needed*. The Finnish food industry is of the view that with Article 13 claims, textbook data and nutrition references should suffice, and no new scientific studies on the product itself should be required. The food supplement industry wishes that studies carried out with ingredients should suffice. The entrepreneurs acknowledge the need for product-specific proof on Article 14 claims, i.e. claims pertaining to the reduction of the risk of disease and the health and development of children.¹²²⁵ The Finnish list was based on fairly strict scientific criteria, as Finnish scientists share the view that claims must not be approved without convincing evidence. However, the Commission seems to be even stricter and in autumn 2008 it seems that few Finnish claims will be accepted. It remains to be seen whether the finished Community list will be very short and abolish many of the health claims that are currently used.

After discussing the process for establishing the Community list, we now turn to legal issues related to adding claims to the list *after* 2010. An application is needed for these claims, which are:

- a) based on newly developed scientific evidence and/or
- b) which include a request for the protection of proprietary data.

Any Article 13 claims submitted to the EU list *after* the publication of the first list in 2010 will have to be examined by the EFSA and approved by the Commission and Member States¹²²⁶. A food business operator intending to use a health claim not included in the Article 13 list may apply for the inclusion of the claim in that list¹²²⁷ according to the procedure stipulated in *Article 18* of the Regulation. Article 18 applies to claims that are based on newly developed scientific evidence and/or include a request for the protection of proprietary data¹²²⁸.

¹²²² Report on health claims used in marketing of foodstuffs in Finland 2007, 17.

¹²²³ Report on health claims used in marketing of foodstuffs in Finland 2007, 20.

¹²²⁴ Report on health claims used in marketing of foodstuffs in Finland 2007, 20.

¹²²⁵ Report on health claims used in marketing of foodstuffs in Finland 2007, 24.

¹²²⁶ Through the Committee procedure according to Article 25 of the Regulation.

¹²²⁷ Regulation 1924/2006/EC, Article 18(1).

¹²²⁸ Article 13(5) of the Regulation.

The application for the inclusion shall be submitted to the national competent authority of a Member State. The application shall include the reasons for the request, along with the following data:

- (a) the name and address of the applicant;
- (b) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
- (c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;
- (d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
- (e) a copy of other scientific studies which are relevant to that health claim;
- (f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
- (g) a summary of the application.¹²²⁹

The Member State will send the application to the EFSA to be assessed, and to the Commission and the Member States for information. The EFSA shall perform scientific assessment of the claim (within five months) and subsequently issue its opinion to the applicant, to the Commission and to the Member States, and publish it.¹²³⁰

If the EFSA opinion is in favour of the applicant, the Commission shall take a decision on the application (within two months), taking into account:

- the EFSA opinion,
- any relevant provisions of Community law,
- *other legitimate factors* relevant to the matter under consideration, and
- results of consultation with the Member States.¹²³¹

According to the EFSA pre-submission guidance of March 2007 (revised August 2007), *Article 18 procedure is not applicable* before the aforementioned Community list of permitted health claims is adopted.¹²³² This would have meant January 2010. However, the EFSA seems to have changed their mind and started to take in Article 18 applications already in February 2008. This is confirmed by the December 2007 Guidance from the Scientific Committee on Food Safety and Animal Health of the European Commission¹²³³: “From 1 February 2008 Member States can send valid applications to the EFSA for the scientific assessment in accordance with Article 18(3)”. However, the EFSA has not yet given guidance on how to draft Article 18 claims.

¹²²⁹ Regulation 1924/2006/EC, Article 15(3).

¹²³⁰ Regulation 1924/2006/EC, Article 18(3).

¹²³¹ Regulation 1924/2006/EC, Article 18(4).

¹²³² EFSA Pre-submission Guidance for Applicants Intending to Submit Application for Authorisation of Health Claims made on Foods. Publication Date: 14 March 2007 Last updated (Rev.): 8 August 2007, page 4.

¹²³³ Scientific Committee Claim Guidance 2007, 12.

Article 18 is similar to Article 13, with the exception that the evidence submitted is “newly developed scientific evidence.” The legislation does not define “new”, but it is understood as scientific evidence developed after January 31, 2008 (the deadline for Article 13 submissions). Because the EFSA started to grant applications via the Article 18 route from the beginning of February 2008, some companies might consider withdrawing under Article 13 and resubmitting under Article 18. This is because the Article 18 procedure is faster than the Article 13 procedure as the EFSA and the Commission will have to abide by the time limits of five and two months. However, if the data was published by either an applicant or a third party before January 31, 2008, the data is not ‘new’ and therefore belongs under Article 13.¹²³⁴ If the claim is based on proprietary data, Article 18 applies regardless of the time when the data was established.

Like the borderline between nutrition claims and function claims, *the borderline between function claims and disease risk reduction claims* has also already shown to be problematic. The Commission Scientific Committee Guidance of December 2007¹²³⁵ clarifies the issue: If a risk factor of a disease is merely *mentioned*, without stating, suggesting or implying its *reduction*, the claim should be considered a function claim (Article 13 claim). An example of a function claim is given: *maintains* [naming normal vital function of the body]. If reduction of a disease risk factor is claimed, the claim should be considered an Article 14 claim regardless of whether the name of the disease itself is mentioned. An example is given: *lowers* [naming risk factor].¹²³⁶

5.3.3.5.3 Article 14: Disease Risk Reduction Claims and Claims Related to Children’s Health

As stated above, two Community lists of authorised claims will be created. The list based on Article 14 will include reduction of disease risk claims and claims relating to children’s development and health. These claims are evaluated by EFSA according to the procedure laid down in Articles 15, 16, 17 and 19 of the Regulation. These claims may be made only if they have been authorised according to the relevant procedure and included in the Community list for such claims. The list of claims will include the conditions for the use of the claims.¹²³⁷ The claims are of the type ‘compound A reduces the risk of heart disease’.

In addition to the general requirements for claims and general requirements for health claims, reduction of disease risk claims must be joined with another additional piece of information: The labelling, presentation or advertising shall bear a statement indicating that the disease to which the claim is referring has *multiple risk factors* and that altering one of these risk factors may or may not have a beneficial effect.¹²³⁸

Article 15 of the Regulation stipulates the details of the application for authorisation. The application shall be sent to the national competent authority of a Member State. The national competent authority shall send the application as a whole to EFSA. EFSA shall send the application to other Member States and the Commission, and publish the summary of the application.

¹²³⁴ Tallon 2008.

¹²³⁵ Guidance on the Implementation of Regulation N° 1924/2006 on Nutrition and Health Claims Made on Foods. Conclusions of the Standing Committee on the Food Chain and Animal Health. 14 December 2007.

¹²³⁶ Scientific Committee Claim Guidance 2007, page 13.

¹²³⁷ Regulation 1924/2006/EC, Article 14(2).

¹²³⁸ Regulation 1924/2006/EC, Article 14(2).

The EFSA has provided guidance on the details of the application. The EFSA published its much-anticipated guidelines on disease risk reduction claims in July 2007¹²³⁹. The 44-page document, prepared by the Scientific Panel on Dietetic Products, Nutrition, and Allergies, can be accessed via EFSA's website¹²⁴⁰. Based on EFSA guidelines, food companies have put systems in place to ensure they are in as strong a position as possible. Companies want to ensure that existing claims can still be made, and to prepare for future disease risk reduction claims¹²⁴¹.

The EFSA guidance applies to health claims related to the consumption of a food category, a food, or its constituents, including a nutrient or other substance, or a combination of nutrients/other substances. The purpose of the guidance is to assist applicants in preparing and presenting their applications for authorisation of health claims which fall under Article 14 of the Regulation, i.e. reduction of disease risk claims and claims referring to children's development and health.

The EFSA Guidance "presents a common format for the organisation of the information to assist the applicant in the preparation of a well-structured application". According to EFSA, adherence to the format will facilitate them to do its work in an effective and consistent way. EFSA "strongly advises" the applicant to adhere to the Guidance for preparing their application. A ready-to-use word-format of the application is also provided^{1242, 1243}

The application for an Article 14 claim shall include the following data¹²⁴⁴:

- (a) the name and address of the applicant;
- (b) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
- (c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in the Regulation;
- (d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
- (e) a copy of other scientific studies which are relevant to that health claim;
- (f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
- (g) a summary of the application.¹²⁴⁵

¹²³⁹ Opinion of the Panel on dietetic products, nutrition and allergies (NDA) on a request from the Commission related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim. Adopted 06/07/2007. The draft opinion was published in May 2007, after which stakeholders had a chance to give their comments before adoption of the final version.

¹²⁴⁰ EFSA web page at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm.

¹²⁴¹ Nutraingredients.com. Europe. <http://www.nutraingredients.com/news/ng.asp?n=76579-efsa-health-claims>.

¹²⁴² Available at: http://www.efsa.europa.eu/en/science/nda/Pre_submission_guidance/nda_technical_guidance.html.

¹²⁴³ EFSA pre-submission health claim guidance for applicants 2007, 5.

¹²⁴⁴ The same data as required when adding claims to Article 13 list.

¹²⁴⁵ Regulation 1924/2006/EC, Article 15(3).

EFSA shall make the Summary of the Application available to the public. The Summary of the Application should be presented in a standardized form. Therefore it is *mandatory* to use the form provided in the Appendix B of the EFSA Guidance. The summary The Summary shall be preferably presented in English and shall not contain parts which are considered to be confidential as summaries are published on the EFSA website.¹²⁴⁶

Now we turn to what happens after the applicant has done his share. After receiving an application, *EFSA has five months to give its opinion*¹²⁴⁷. In order to prepare its opinion, the Authority shall verify:

- (a) that the health claim is substantiated by scientific evidence;
- (b) that the wording of the health claim complies with the criteria laid down in the Regulation.¹²⁴⁸

EFSA shall forward its opinion to the Commission, the Member States and the applicant. The opinion shall include a report describing assessment of the health claim and stating the reasons and grounds for EFSA opinion. Article 16(4) particularly¹²⁴⁹ must be listed in an opinion in favour of authorising the health claim. EFSA shall make its opinion public, and the applicant and the public may make comments to the Commission within 30 days from such publication.

After receiving the EFSA opinion, *the Commission has two months to submit a draft decision*¹²⁵⁰ to its Standing Committee on the Food Chain and Animal Health. When drafting the decision, the Commission shall take into account:

- EFSA opinion,
- any relevant provisions of Community law, and
- other legitimate factors relevant to the matter under consideration.

Where the draft decision is not in accordance with the EFSA opinion, the Commission shall provide an explanation for the differences. *Use of the term “other legitimate factors” grants the Commission wide discretionary powers to include other than scientific factors in their decision-making.* A draft decision to amend the lists of permitted health claims shall include

¹²⁴⁶ EFSA pre-submission health claim guidelines to applicants 2007, 5-6.

¹²⁴⁷ Regulation 1924/2006/EC, Article 16(1).

¹²⁴⁸ Regulation 1924/2006/EC, Article 16(3).

¹²⁴⁹ (a) the name and address of the applicant;

(b) the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics;

(c) a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use;

(d) where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising.

¹²⁵⁰ The decision on whether or not to include the claim on the Community list.

the particulars referred to in Article 16(4)¹²⁵¹. The Standing Committee of the Food Chain and Animal Health shall adopt a final decision in accordance with the Committee procedure. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the Official Journal of the European Union.

Above, we have discussed the borderline between nutrition claims and health claims, and the borderline between function claims and disease risk reduction claims. Also *the distinction between claims referring to children's development and health and other health claims* has required further clarification by the Commission. As stated above, Article 14 covers claims that refer to "children's development and health". The term "children", however, is not defined in the Regulation. Commission Guidance states that it "should be understood as reaching *the end of the growth period*", and that "an *indicative age limit of 18 years* can be mentioned, but this indication does not intend to define children in the frame of the Regulation". "Infants" and "young children", as defined in Directives on dietetic foods, are subgroups of "children".¹²⁵²

According to Commission Guidance, the following health claims should be considered as claims referring to children's development and health (and as such, Article 14 claims):

- "Health claims *solely referring to the development and health of children*, and where *the scientific substantiation is only valid for children*. In this case, the scientific substantiation consists of data obtained on *studies conducted with children*." An example of this kind of claim is given: "calcium is good for children's growth".
- Health claims used on *products intended exclusively to children*, like follow-on formula, processed cereal-based foods and baby foods for young children^{1253, 1254}

The following health claims should be considered function claims (Article 13 claims): "Claims referring to the role of a nutrient or other substance in growth, development and to the functions of the body where *the scientific substantiation covers the entire life span, or more than the children population group*." An example is given: "for children and pregnant women". In this case, the scientific substantiation must cover the children population group and the pregnant women population group.¹²⁵⁵

¹²⁵¹ The same information that must be included in a favourable EFSA opinion: (a) the name and address of the applicant; (b) the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics; (c) a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use; and (d) where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising.

¹²⁵² Scientific Committee Claim Guidance 2007, 13-14.

¹²⁵³ These are dietetic foods under Directive 89/398/EEC. It was stated above that the Nutrition and Health Claim Regulation does apply to follow-on-formulae and baby foods, but not to infant formulae.

¹²⁵⁴ Scientific Committee Claim Guidance 2007, 14.

¹²⁵⁵ Scientific Committee Claim Guidance 2007, 14.

5.3.3.5.4 Data Exclusivity of Health Claims

Health claims included in the Community lists may be used, in conformity with the conditions applying to them, *by any food business operator*¹²⁵⁶. An important limitation to this rule is the *five-year exclusivity of proprietary data*: scientific data and other information in the application may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation. This applies both to function claims authorised through Article 18 and disease risk reduction claims authorised through Article 14. The conditions for this exclusivity of data are:

- (a) the scientific data and other information *has been designated as proprietary* by the prior applicant at the time the prior application was made; and
- (b) the prior applicant *had exclusive right of reference to the proprietary data* at the time the prior application was made; and
- (c) *the health claim could not have been authorised without the submission of the proprietary data* by the prior applicant.¹²⁵⁷

The subsequent applicant may use proprietary data as grounds for his application, if he has agreed with the prior applicant that such data and information may be used. The subsequent applicant can always obtain authorisation for the same claim, if he can do it without reference to the proprietary data of the original applicant. Exclusivity of data might also be ended before the five-year period, if the Commission takes a decision that a claim could be or could have been included in the lists without the proprietary data¹²⁵⁸. This means that data protection only blocks competitors in cases where the scientific evidence never was and still isn't anywhere else to be found.

The five-year exclusivity is regarded as a balance between A) promoting research in health foods and B) avoiding unnecessary repetition of research efforts. Preamble 32 of the Regulation states: "In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application." The explanation continues: "This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials, and to facilitate access to claims by small and medium-sized enterprises (SMEs), which rarely have the financial capacity to carry out research activities."

Exclusivity of data to support a health claim is similar to an intellectual property right. Similar limited exclusivity of data has been proposed for the novel foods application process. A functional food sometimes has both novel ingredient(s) and novel health claim(s). It would often be practical to evaluate the safety element (novel food regulation) and the efficacy element (health claim regulation) in a single procedure. If this kind of evaluation procedure is not created, at least the two procedures will in the future apply the same principles regarding data protection.

¹²⁵⁶ Regulation 1924/2006/EC, Article 17(5).

¹²⁵⁷ Regulation 1924/2006/EC, Article 21(1).

¹²⁵⁸ Regulation 1924/2006/EC, Article 21(2).

5.3.3.5.5 Transitional Measures for Nutrition and Health Claims

All *new products with new claims* must be approved according to Articles 13 and 14 of the Regulations and added to Community lists before use. There are transitional measures for products already on the market and for claims already in use. Non-complying foods placed on the market or labelled prior to 1st July 2007 may be marketed until their expiry date, but not later than 31 July 2009.¹²⁵⁹ This means no illegal labels can be printed after 1st July 2007, but the old ones can be used for two years.

With regard to *nutrient profiles*, foods may be marketed until twenty-four months following adoption of the relevant nutrient profiles and their conditions of use.¹²⁶⁰ As the Commission has until 19 January 2009 to complete the profiles, they will not come into full effect until 2011.

Nutrition claims which have been used in a Member State before 1 January 2006 in compliance with national provisions applicable to them and which are not included in the Annex, may continue to be used until 19 January 2010. Single Member States can do this under the responsibility of food business operators and without prejudice to the adoption of safeguard measures.¹²⁶¹ An additional authorisation procedure is created for *nutrition claims in the form of pictorial, graphic or symbolic representation*, used according to criteria elaborated by national rules. Member States shall communicate such nutrition claims with the applicable national rules and scientific data in support of such rules to the Commission by 31 January 2008. The Commission shall, in accordance with the Committee procedure, adopt a Decision concerning the use of such claims. Nutrition claims not authorised under this procedure may continue to be used for twelve months following the adoption of the Decision.¹²⁶²

Health claims other than those referring to the reduction of disease risk and to children's development and health can be made until the adoption of the list, under the responsibility of food business operators and without prejudice to the adoption of safeguard measures by single Member States. The Commission will establish the list by 31 January 2010. This means old function claims can be still be used while all claims referring to disease risk reduction or children's health must be authorised by the Commission.

There is an additional authorisation procedure for old health claims. These *are health claims that have been used in compliance with national provisions, and been the subject of evaluation and authorisation in a Member State*. Member States were to communicate these claims¹²⁶³ with a report evaluating the scientific data in support of the claim to the Commission. After consulting the EFSA, the Commission shall, in accordance with the Committee procedure, adopt a Decision concerning the health claims authorised in the aforesaid manner. Health claims not authorised under this procedure may continue to be used for six months following the adoption of the Decision.¹²⁶⁴ Thus the marketers that have already undergone one authorisation procedure will not have to repeat it. The Member State will do it on their behalf.

Different rules apply to health claims which have been in use but which have *not* been the subject of evaluation and authorisation in a Member State. Such claims may continue to be

¹²⁵⁹ Regulation 1924/2006/EC, Article 28(1).

¹²⁶⁰ Regulation 1924/2006/EC, Article 28(1).

¹²⁶¹ Regulation 1924/2006/EC, Article 28(3).

¹²⁶² Regulation 1924/2006/EC, Article 28(4).

¹²⁶³ By 31 January 2008.

¹²⁶⁴ Regulation 1924/2006/EC, Article 28(6).

used provided an application was made pursuant to the Regulation before 19 January 2008. Health claims evaluated pursuant to this procedure may continue to be used for six months after a negative decision is given. Marketers saw this as an opportunity to buy extra time if deemed necessary, as it takes time for the EFSA and the Commission to come up with final decisions. Therefore, in reality, old health claims may exist in 2009.

The nutrition and health claim Regulation also applies to trade marks and other brand names which may be construed as nutrition or health claims¹²⁶⁵. For trade marks, the transitional period is the longest, 15 years. Products bearing trade marks or brand names existing before 1 January 2005 may continue to be marketed until 19 January 2022¹²⁶⁶. Existing brand names suggesting health benefits (such as promises of weight loss) that do not meet the requirements of the Regulation must be phased out and removed from the market.

5.3.3.6 Implications of the European Claim Legislation

The claim legislation means, at least in principle, less trouble for those marketers that use established function claims. The Member States, the EFSA and the Commission will draw up the list, after which any marketer can use the claims, *provided that the product corresponds to the claim*. This means the marketer is still responsible for evaluating whether the established claim applies to a single product.

Use of *new function claims* or *disease reduction claims* will require specific authorisation by the Commission, following scientific assessment and verification of the claim by the EFSA. After a claim has been added to the list, other entrepreneurs can use the claim in marketing, unless the claim is based on proprietary data. The 5-year data protection rules might open new market opportunities for the ‘claim-owners’. *Health claims could be licensed as intellectual property*. This means a claim-owner might agree that another marketer can use the claim in return for payment of a fixed sum or royalties.

It will be interesting to see what will be on the first Article 13 list of established claims. Will there, for example, be claims that are verified by long-time Chinese use? According to the European Botanical Forum (EBF), botanicals that rely on evidence of traditional use for health claim substantiation face an uncertain future. This is because the EFSA guidelines fail to acknowledge the traditional use criteria. The EFSA guidance document makes no reference whatsoever to “traditional use” or “history of use” for botanical products in food and food supplements.

The question of established claims is rather similar to the question of safety of novel foods, because both pieces of regulation can be discriminatory based on their basic presumptions. Foods are not novel and thus presumed safe, if they have been used in Europe. It might be that health claims are more easily considered established, if European scientists and consumers in a European country have accepted them. Coming from China or America, for example, might cast an extra burden of proof onto the marketer. An ‘exotic’ product is probably considered novel, and the health claim might also more likely be considered unestablished. In principal, the legal requirements for safety and efficacy are the same for all the products, and the food business operator is always

¹²⁶⁵ Regulation 1924/2006/EC, preamble 4.

¹²⁶⁶ Regulation 1924/2006/EC, Article 28(2).

responsible for the product complying with the law. However, if you are European, you have the advantage of European legislators undertaking some of the work.

In the comparison of (functional) foods with herbal medicinal products, European information is considered more valuable than, for example, Asian and American information. A product can be registered as a traditional herbal medicinal product, if it fulfils certain other conditions and has been used for *30 years, at least 15 of which were in Europe*. Safety and efficacy of these traditional products are considered adequately proven and they are allowed to access the market. The legislation seems to be based on a basic psychological premise; trust the familiar and be wary of the unfamiliar.

Boal suspects that the expense and administration involved in the pre-market assessment process of health claims may prevent some companies from presenting novel claims. But given the great potential of the market, several companies may judge the investment worthwhile. Either way, the new regulation makes the situation much clearer.¹²⁶⁷ There is only one route in Europe for presenting health claims; all other health claims are illegal.

The CIAA demanded EU-wide interpretative guidelines on the regulation. This is to ensure a level playing field of enforcement authorities and operators and thus guarantee the proper functioning of the internal market.¹²⁶⁸ The EFSA has already given its guidance on Article 14 applications. They will also provide guidelines on inclusion of health claims in the Article 13 list which will include claims that are based upon newly developed scientific evidence and/or which include a request for the protection of proprietary data. Guidelines are also expected on nutrition profiles.

The Regulation as such is not enough: several guidance documents and opinions are needed to resolve how the Regulation is implemented. The role of *EFSA soft law and Commission soft law* is thus extremely important. The EFSA “strongly advises” the applicants to adhere to their guidelines. In practice, it is the EFSA who decides on the health claim procedures. The Commission will have to rely on the EFSA on scientific issues, thus the EFSA has an important role as a non-partial scientific assessment body. The Commission can, however, base their decision on “other legitimate factors”, not merely the scientific opinion from the EFSA. This means there is room for political considerations. This is typical of European food law: it is based on science, but not merely on science. European operators seem to have more faith on the EFSA than on the Commission as regards impartiality.

The Regulation poses challenges to post-market supervisory authorities in the Member States. Even though local food control authorities do not need to evaluate the adequacy of the claims (as it is done pre-market at the EU level), they must still be able to ensure that the preconditions for use of the claims are fulfilled. This refers to the additional information that must accompany the claim and verification of adherence to nutrition profiles that must be fulfilled.¹²⁶⁹ There will still also be illegal nutrition claims, health claims, and also medicinal claims on foods, which the authorities must eradicate

¹²⁶⁷ Boal 2006.

¹²⁶⁸ Review of CIAA Priorities and Objectives for Better Regulation

¹n light of the Commission proposals to simplify EU legislation. CPT/003/07E-Final Brussels, 28 February 2007 Page 5.

¹²⁶⁹ Report on health claims used in marketing of foodstuffs in Finland 2007, 25.

5.3.4 Chinese Rules on Nutrition and Health Claims

5.3.4.1 Names of Health Related products

China has new legislation that is common to all health related products, including food among other products.¹²⁷⁰ This legislation includes:

- Working Procedure of Examination and Approval on Health Related Products of Ministry of Public Health;
- Rule of Evaluation and Examination Committee of Health Related Products of Ministry of Public Health; and
- Regulation on *Nomenclature*¹²⁷¹ of Health Related Products.

Articles of the Procedure discuss the tasks of different authorities¹²⁷². The Rule of the Committee also contains procedural rules. The Nomenclature Regulation stipulates substantial rules on names. ‘Health related products’ refers to food, cosmetics, products related to hygiene and safety of drinking water, disinfectant and disinfecting tools and other products related to human health; which are examined and approved by the Ministry of Public Health according to the following legislation:

- Food Hygiene Law of the People’s republic of China¹²⁷³,
- Regulation on Hygiene Supervision of Cosmetics,
- Regulation on Health Food Administration,
- Regulation on Hygiene Administration and Supervision of Drinking Water,
- Regulation Administration of Disinfecting, and
- Other laws, decrees and regulations.¹²⁷⁴

The Nomenclature Regulation has been enacted to protect the consumer’s right to accurate information and is applied to, among other things, health food. . The Committee examines the names of the health related products. The nomenclature of a health related product must meet the following requirements¹²⁷⁵:

¹²⁷⁰ In EU law, there is no legal product safety category between general product safety and food safety. Chinese law on health-related products is here presented in between general product safety and general food safety. In Germany, foodstuffs and cosmetics are governed by the same law. Also in the United States, foodstuffs, cosmetics, and drugs are governed by the same law.

¹²⁷¹ This means names.

¹²⁷² All health related products are evaluated and examined by a committee under the Ministry of Public Health, the composition of which is regulated in the Rule on the Committee. The Ministry also has a Health Related Products Inspection Institute, which undertakes inspections of samples sent by applicants. The basic principle manifested in the rules on the authorities is that openness and impartiality are guaranteed in the application procedure and the acceptance of health related products.

¹²⁷³ Now replaced by the Food Safety Law.

¹²⁷⁴ Article 2 of the Working Procedure.

¹²⁷⁵ Nomenclature on health related products, article 4.

1. It must conform to related laws, regulations, decrees and standards,
2. It must reflect the property of product; it must be concise, easily understood, and conform to Chinese convention,
3. The name consists of trademark, model¹²⁷⁶, general name, and name of property, in this order.

The trademark, model, general name and name of property must meet the following requirements¹²⁷⁷:

1. The name must conform to related regulations and adopt a registered trademark. A health related product cannot use a trademark which exaggerates functions or misleads consumers.
2. The model should indicate the characteristics of products, such as material, volume, capacity and advancement.
3. The general name should be accurate and scientific, and indicate major materials, major effective components or have words of function, but *not indicate or hint of a curing effect*.
4. The name of property should indicate the objective form of product and should not use the abstract name. For those products which consumers are familiar with, the name of property can be omitted, such as lipstick etc.

Article 7 lists additional requirements: if the product has the same trademark, same general name, and same name of property but different taste or it is produced for special groups of people, the difference should be indicated after the name of property.

It is forbidden to use the following contents in nomenclature of a health related product¹²⁷⁸:

1. professional terms not easily understood, and dialects,
2. false, exaggerating and extreme terms such as highly effective, universal and “xx” generation,
3. vulgar or superstitious terms,
4. *the name of approved medicines*,
5. letters of foreign language, Pinyin of Chinese and symbols. If it is a trademark or letters and symbols of a foreign language that have to be used, it should be mentioned in specification in Chinese.

The Chinese name of an imported health related product should correspond to the foreign name as much as possible. The name can be translated according to meaning, pronunciation, or both. Generally, the foreign name is translated according to its meaning.¹²⁷⁹

¹²⁷⁶ Name of a tool should include the model of the product. This is related to disinfecting tools that are also included in the concept of health related products.

¹²⁷⁷ The list is given in Article 5 of the Regulation on Nomenclature of Health Related Products, but not in this order.

¹²⁷⁸ Article 8.

¹²⁷⁹ Article 9.

5.3.4.2 Nutrition Claims

Until recently, nutrition claims have not been regulated in China. In November 2007, the Chinese Ministry of Health issued Administrative Measures on Food Nutrition Labelling¹²⁸⁰. The Measures are applicable from 1st May 2008. Nutrition labelling and nutrition claims are regulated by one single instrument.

The new regulation stipulates the definition of food nutrition labelling and its scope, nutrition declaration and nutrition claim. The three technical annexes stipulate definition of nutrition ingredients, rounding rules, nutrients reference values, the conditions and terms of nutrition claims.¹²⁸¹ Companies are not allowed to state their products are high in calcium, iron or low in fat unless they meet certain strict criteria. They must not make false claims nor exaggerate the nutritional benefits of the product. The prohibition of medicinal claims is also repeated: labels must also not make direct or indirect claims of curing illness.¹²⁸²

5.3.4.3 Health Food Efficacy: the 27 Claims

The Health Food Regulation was discussed above in chapter 4 with regard to the safety aspect. Here we focus on marketing, and particularly on what can be claimed. Health food is defined as a food that has *a specific health function*, is suitable for *certain groups of people*, but is *not for curing a disease*.¹²⁸³ In Article 23 of the Food Hygiene Law, misleading advertising of health foods was prohibited: The content of the product description shall be accurate. The functions and ingredients of the product shall be identical with the information given in the product description and there shall be no false information. Article 51 of the new Food Safety Law states the same rules in new words. Claims that refer to prevention or treatment of disease (medicinal claims) are prohibited on health foods. Suitable and unsuitable user groups of the health food must be given, as also the functional ingredients and their content.

As stated above, the Health Food Regulation establishes minimum safety and efficacy requirements for health foods as follows:

- raw materials and final products must comply with food hygiene requirements and shall not cause any acute, sub chronic, or chronic harm to human body,
- necessary animal and/or human tests must have confirmed a clear and stable health effect,
- formulation and dosage must be based on scientific evidence (the functional ingredient should be identified but when that is impossible, at least the raw materials that cause the effect shall be listed),
- *therapeutic effects shall not be claimed* in labelling or advertising.¹²⁸⁴

¹²⁸⁰ 22 pages, in Chinese.

¹²⁸¹ WTO TBT/SPS notification. <http://www.tbt-sps.gov.cn/sites/English/News/Lists/news/DispForm.aspx?ID=60>.

¹²⁸² Reuters Beijing January 11 2008.

¹²⁸³ Article 2.

¹²⁸⁴ Health Food Regulation, Article 4. Huang – Lapsley 2005, 266.

There is certain mandatory information that must be given to consumers on health foods. According to the Health Food Regulation¹²⁸⁵, the label and specification of health food must contain the following details: role of the product in health protection, suitable user groups, optimal dosage, storage method, name and quantity of effective components¹²⁸⁶, order number of health food certificate, and the health food symbol. Names of health foods should be accurate, scientific and should not use names of peoples, names of places, names that are misleading or exaggerating, or names of minor effective components¹²⁸⁷. Labels and advertisements of health foods must be accurate and compatible with the nature and quality of the products. There shall be no referrals to therapeutic effects. It is also forbidden to use superstition in health food advertisement.¹²⁸⁸

It is important to notice that in China, *only health foods can bear health claims*. Regular foods cannot bear health claims. On the other hand, health foods cannot bear medicinal claims. This way the health food regulation separates normal foods from health foods, foodstuffs from medicines, and food advertising from medicine advertising. To make the separate functions clear, health foods must bear the advice: ‘this product cannot substitute any medicine’¹²⁸⁹.

There are currently 27 possible functions and claims for health foods, with other functions not accepted:

1. Enhancing immune function
2. Assisting in blood lipids reduction
3. Assisting on blood sugar reduction
4. Anti-oxidation (delay of aging)
5. Assisting in memory improvement
6. Reducing eye fatigue
7. Facilitating lead excretion
8. Thinning throat mucus (moistening of throat)
9. Assisting in hypertension (blood pressure) reduction
10. Enhancing sleep
11. Promoting lactation
12. Alleviating physical fatigue
13. Enhancing anoxia endurance
14. Assisting protection against irradiation hazard
15. Weight reduction
16. Enhancing child growth and development
17. Increasing bone density
18. Alleviating nutritional anaemia
19. Assisting in protection against liver chemical injury
20. Alleviating acne
21. Eliminating skin pigmentation

¹²⁸⁵ Article 21.

¹²⁸⁶ If components of effective function cannot be determined under present conditions, names of major raw materials having a health protection function should be listed.

¹²⁸⁷ Health Food Regulation, Article 22.

¹²⁸⁸ Health Food Regulation, Article 23.

¹²⁸⁹ Functional Ingredients December 2005 China News. Available at www.functionalingredientsmag.com.

22. Improving skin moisture
23. Improving skin oil content
24. Regulating gastrointestinal flora
25. Facilitating digestion
26. Alleviating constipation
27. Assisting in protection against gastric mucosa injury.¹²⁹⁰

The Chinese health claim categories cover all the important claims that are most interesting to Western functional food developers. The Ministry of Health revised the procedures for efficacy evaluation in 2003, when the current list of 27 functions/claims came into force. Cosmetic claims were separated into four different claims instead of just one (claims 20-23 above). Similarly, stomach health claims were separated into four different claims (claims 24-27 above).¹²⁹¹

It is not possible to market an all-purpose health food: a health food with the same recipe is not allowed to be used for the application of more than *two functions*. Applications for supplementary functions are not accepted.¹²⁹² Most of the important claims interesting to Western developers of functional foods are included in the list. Two important claim types are missing: claims related to cancer, and claims related to sexual functions. Some of the listed health issues are not familiar to the European people as they are not a part of European health policies. It is therefore not likely that a Western company will focus research and product development efforts particularly on these issues. Companies often build on their own experience and competencies and are best at what is familiar to them.

In 2002, 60 percent of authorised health foods focused on *three functions*: immune regulation, regulating blood pressure, and anti-fatigue. Health foods were not often in regular food form; instead they were primarily in the form of liquid, capsule, tablet, or powder. It is noteworthy, that in about 90 percent of health foods, the active ingredients of the products were related to Traditional Chinese Medicine.¹²⁹³ Today, other types of health foods are also emerging. For example, probiotic products are gaining interest. In 2002, 90 percent of health foods were marketed by Chinese companies, 10 percent were imported¹²⁹⁴.

It is noteworthy that many of the claims are currently formulated in a way that considers other factors than diet in improving one's health. The verb "assist" is now used in 6 claims. For example, one cannot say that a product lowers hypertension; instead it is allowed to say that it assists in hypertension alleviation. This approach is similar to the European rules on health claims reminding the consumer of lifestyle factors.

The list of allowed claims would not give much guidance without rules on scientific substantiation of the claims. According to the current rules on health food efficacy, *animal trials* are required for 22 of the 27 claims. Animal trials are *not required* for claims on:

¹²⁹⁰ Ministry of Health Notification 2003, point A.

¹²⁹¹ Huang – Lapsley 2005, 264.

¹²⁹² Ministry of Health Notification 2003, points B and C.

¹²⁹³ Wang et al. 2003.

¹²⁹⁴ Huang – Lapsley 2005, 263.

- alleviating eye fatigue,
- cosmetic claims: alleviating acne, eliminating skin pigmentation, improving skin moisture, and improving skin oil content.¹²⁹⁵

Human feeding trials are now required for 20 claim categories. Human trials are *not required* for claims on:

- enhancing immune function,
- enhancing sleep,
- alleviating physical fatigue,
- enhancing anoxia endurance,
- assisting in protection against irradiative hazard,
- increasing bone density,
- assisting in protection against liver chemical injury.¹²⁹⁶

If both animal and human tests are required, human tests are done after getting a positive result with animal tests. Before a human feeding trial can be started, it must receive approval from an ethical committee. The samples submitted for functional evaluation must have already passed safety evaluation.¹²⁹⁷

The testing parameters and trial designs are precisely regulated for each claim. Here we mention as an example a product, which claims to *assist in hypertension alleviation*. Both animal experiments and human feeding trials are required. Animals to be used are 10-12 week old rats with hypertension. The duration of a feeding experiment is 30-45 days. Testing parameters are body weight, blood pressure, and heart rate. Human trials must be done with 18-65 year-old hypertension patients. Systolic heart pressure should be at least 140 and diastolic at least 90. Testing parameters are the clinical syndrome & signs, blood pressure, and heart rate.¹²⁹⁸

The regulations do not give precise requirements on how effective a product must be. Similarly to the European rules on claims, the regulations only give the scientific criteria that are used in the evaluation of the application. Whether the product is effective enough is a question that the SFDA will have to evaluate on a case-by-case basis.

5.4 General Rules on Medicine Marketing¹²⁹⁹

5.4.1 EU

Next we will discuss the general rules on medicine marketing, including rules on labelling and advertising, without yet going to regulations on medicinal claims. In the EU, labelling

¹²⁹⁵ Huang – Lapsley 2005, 277-281.

¹²⁹⁶ Huang – Lapsley 2005, 277-281.

¹²⁹⁷ Huang – Lapsley 2005, 276.

¹²⁹⁸ Huang – Lapsley 2005, 278. For information on trial designs and testing parameters of other claims, see Huang – Lapsley 2005, 277-281.

¹²⁹⁹ This means rules other than those applicable to claims.

is regulated in Title V and advertising in Title VIII of the Medicinal Products Directive 2001/83/EC¹³⁰⁰. Advertising is “any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products”¹³⁰¹.

Like foodstuffs, there is certain information that a marketer *must give* to the consumer. These are to be given in *the label and in the package leaflet* of a medicinal product. Certain information must appear on the outer packaging of medicinal products or, where there is no outer packaging, the immediate packaging. These are: name of the medicinal product, qualitative and quantitative composition in respect of active substances, pharmaceutical form and contents by weight, route of administration, list of ingredients, expiry date, special storage precautions, disposal of unused medicinal products or waste materials, authorisation number and manufacturing batch number, and special warnings.¹³⁰² These particulars must be legible and clearly comprehensible¹³⁰³.

Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain: the price, the reimbursement conditions of social security organisations, the legal status for supply, identification and authenticity.¹³⁰⁴ In Finland for example, the Nordic number is required on the label of all medicinal products, except radio pharmaceuticals and herbal remedies. It is written as “Vnr XX XX XX”. Products containing inflammable material must contain the international warning symbol (flame), and products that may reduce the ability to drive or operate machines must have a warning triangle.¹³⁰⁵

The packaging of all medicinal products must contain *a package leaflet*, unless all the information required features directly on the outer packaging or on the immediate packaging. The package leaflet must include certain particulars. These are: name of the medicinal product, therapeutic indications, information necessary before taking the medicinal product, the

¹³⁰⁰ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

¹³⁰¹ It includes in particular: “the advertising of medicinal products to the general public, advertising of medicinal products to persons qualified to prescribe or supply them, visits by medical sales representatives to persons qualified to prescribe medicinal products, the supply of samples, the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal, sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products, sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith”. Article 86(1) of the Directive.

¹³⁰² Article 54 of the Directive.

¹³⁰³ Article 56 of the Directive.

¹³⁰⁴ Article 57 of the Directive.

¹³⁰⁵ Notice to Applicants. Guideline on the packaging information of medicinal products for human use authorised by the Community. March 2007. Included in The Rules governing Medicinal Products in the European Community. Page 18.

necessary and usual instructions for proper use, description of the adverse reactions, reference to the expiry date and date on which the package leaflet was last updated.¹³⁰⁶

Now we turn to actual advertising, voluntary messages of the marketer. First of all, advertising of a medicinal product *must encourage rational use of the product and may not be misleading*.¹³⁰⁷ All advertising to the general public of a medicinal product must be clearly identifiable as such and must include the following *minimum information*: a) name of the medicinal product, b) the information necessary for correct use of the medicinal product; c) an express, legible invitation to carefully read the instructions on the package leaflet.¹³⁰⁸

The Medicinal Products Directive 2001/83/EC distinguishes between advertising to doctors and pharmacists, and advertising to the general public. Advertising a medicinal product to persons qualified to prescribe or supply such products “shall include essential information compatible with the summary of product characteristics”¹³⁰⁹. Advertising of medicines to the general public is more restricted and more precisely regulated. It may not include any information which:

- “gives the impression that a medical consultation or surgical operation is unnecessary;
- compares the medicinal product with other treatments or products;
- suggests that the health of the subject can be enhanced by taking the medicine or affected by not taking it;
- is directed exclusively or principally at children;
- refers to a recommendation by scientists, health professionals or persons who, because of their celebrity, could encourage the consumption of medicinal products;
- *suggests that the medicinal product is a foodstuff*, cosmetic or other consumer product;
- suggests that the safety or efficacy of the product is due to the fact that it is natural;
- could, by a description or detailed representation of the case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery; uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body;
- mentions that the medicinal product has been granted a marketing authorisation”¹³¹⁰

¹³⁰⁶ Article 59 of the Directive. Specific provisions apply to the packaging and container of medicinal products containing radionuclides (Article 66), and to the labelling and package leaflets of homeopathic medicinal products (Article 69).

¹³⁰⁷ Article 87 of the Directive.

¹³⁰⁸ Article 89 of the Directive.

¹³⁰⁹ Article 91 of the Directive.

¹³¹⁰ Article 90 of the Directive.

*Prescription medicines*¹³¹¹ cannot be advertised directly to consumers. Neither can medicines that contain *psychotropic or narcotic substances*.¹³¹² Further, the following *therapeutic indications* may not be mentioned in advertising to the general public: tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other tumoral diseases, chronic insomnia, diabetes and other metabolic illnesses¹³¹³. *Direct distribution* of medicinal products to the public for promotional purposes is totally prohibited¹³¹⁴.

The prohibition of direct marketing of prescription medicines does not apply in certain cases. First of all, it does not apply to *vaccination campaigns* carried out by the industry and approved by the competent authorities of the Member States¹³¹⁵.

In 2001, the Commission proposed to allow a five-year trial period for advertising of prescription medicines for three chronic conditions: HIV/AIDS, diabetes and asthma. The proposed experimentation provoked a debate on the benefits and disadvantages of allowing pharmaceutical companies to communicate directly with the public¹³¹⁶, and was rejected by the Parliament and the Council. Stakeholders thought the experiment would be a step towards direct-to-consumer advertising of medicines, which is only allowed in the United States and New Zealand, and against which there are good grounds¹³¹⁷. In Europe, the debate goes on. There are plans on public-private partnerships on patient information, on which consumer organisations have expressed their concerns¹³¹⁸.

The rules prohibiting advertisements on prescription medicines still leave the door open for advertising that does not endorse a certain product, but rather gives information on *a certain medical condition*. Such “consumer guidance” has been carried out by medicine companies, for example, concerning erection disorders¹³¹⁹. In Finland, the National Agency of Medicines has given guidance on what is considered advertising: if the information for instance in a leaflet is intended to support proper use of the product, it is not considered advertising. In this case, also the name of the product can be mentioned. The materials can be considered advertising, if they promote the use of the product or praise benefits of the treatment compared to other treatments.¹³²⁰

¹³¹¹ When granting a marketing authorisation, the competent authorities must determine whether the medicinal product is subject to medical prescription or not. Article 70 of the Directive. This is done based on the criteria set in Article 71 of the Directive: “Medicinal products shall be subject to medical prescription where they: are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or are normally prescribed by a doctor to be administered parenterally.”

¹³¹² Article 88(1) of the Directive.

¹³¹³ Article 88(2) of the Directive.

¹³¹⁴ Article 88(6) of the Directive.

¹³¹⁵ Article 88(4) of the Directive.

¹³¹⁶ Meek 2002.

¹³¹⁷ Mintzes 2001, 1. Reasons to ban DTC medicine advertising include: it raises medicine costs, is not impartial enough, favours new medicines that might not be as safe as the old ones, and promotes the medicalisation of normal life.

¹³¹⁸ Mintzes 2006, 29.

¹³¹⁹ See for example <http://www.miesjanainen.info/>.

¹³²⁰ National Agency for Medicines web page at: http://www.nam.fi/laaketeollisuus/ukk/ukk_lt_markkinointi.html.

To facilitate access to information about medicines available in the EU and to complement the commercial information, the EMEA has launched a public database called EudraPharm. It includes information about the formulation, the strength, and the therapeutic area of the medicine. The EPHA (European Public Health Alliance) criticises this database for not being complete and not covering all the information patients would require, such as full details of clinical trials or the efficiency of the medicine, side effects assessments, etc.¹³²¹

A particular problem with medicine marketing is medicinal product information on the *Internet*. Material on the Internet is not excluded from the definition of an ‘advertisement’. Internet material must fulfil all the normal requirements for medicinal products advertising. According to UK guidelines, if a site has links to another site where additional information on the medicinal product is presented, this other site will also be included in determining whether the marketing is lawful¹³²².

5.4.2 China

The labelling and advertising rules of medicines are fairly similar in China as in Europe. Packages of pharmaceuticals must be labelled and include directions for use in accordance with the regulations. The label or directions must indicate certain mandatory information:

- the generic name of the medicine,
- components,
- specifications,
- the producer,
- registration number,
- batch number of the product,
- production date,
- expiry date,
- indications or major functions,
- directions for use,
- dosage,
- restrictions,
- adverse reactions, and
- precautions.¹³²³

The label must coincide with the approved indications and directions for use, and must be in standard Chinese characters¹³²⁴. Labels cannot be misleading or use unscientific promotional phrases.

¹³²¹ European Public Health Alliance web page at <http://www.eph.org/a/2492>.

¹³²² MHRA: The Medicines Borderline Section and the Internet. Medicines Borderline Section March 2006.

¹³²³ Medicine Administration Law, Article 54.

¹³²⁴ Tsoi 2007.

Advertising can be described as giving voluntary information in order to sell the product. In China, medicinal product advertising is regulated both by the Advertisement law¹³²⁵ and the Medicine Administration Law. There is a *pre-clearance system for medicinal products advertising*, discussed above in chapter 2.

According to Advertisement law, advertisements relating to pharmaceuticals (and medical apparatus and instruments) cannot contain the following:

1. Unscientific assertions or guarantees of efficacy;
2. The rate of treatment efficacy;
3. Comparisons with other medicines or medical apparatuses in efficacy or safety;
4. Titles or images of medical research institutes, academic institutions, medical organisations or experts, doctors or patients; and
5. Other content prohibited by laws and administrative decrees.¹³²⁶

The content of an advertisement for a medicine should be based on the indications approved by the medicine control authorities.¹³²⁷ According to the Medicine Administration Law, the contents of pharmaceutical advertisement must be true, legitimate and free of false claims. The advertisements of non-pharmaceuticals shall not be involved in the publicising of pharmaceuticals. Points 1) and 4) above are repeated by the Medicine Administration Law.¹³²⁸

Several experts are of the view that Chinese law on medicinal products advertising is not functioning properly as misleading medicine advertising has become a real problem in China. Ads on hospitals and medicinal products are very common in China, but according to the State Administration of Industry and Commerce, medicine advertising is the least trusted of all advertising by consumers in 2006¹³²⁹. A government figure says that about 2.5 million Chinese took the wrong medication because of misleading advertising¹³³⁰. The SFDA conducted a national survey of 466 newspapers and 55 local TV channels from January to November in 2006, discovering 48,990 illegal advertisements on medicines¹³³¹.

To counter-attack the described problems, China is tightening control over medicine advertising. The State Administration of Industry and Commerce and the State Food and Drug Administration (SFDA) promulgated:

- 1) the Standards for the Examination and Publication of Medicine Advertisements, and
- 2) the Measures for the Examination of Medicine Advertisements.

¹³²⁵ Advertising Law of the People's Republic of China. Adopted at the Standing Committee of the Eighth National People's Congress of the People's Republic of China on October 27, 1994 to be put Into Effect on February 1, 1995.

¹³²⁶ Advertisement law, Article 14.

¹³²⁷ Advertising Law, Article 15. Medicine Administration Law, Article 61.

¹³²⁸ Medicine Administration Law, Article 61.

¹³²⁹ Hong Kong Trade Development Council. www.tdctrade.com. Business Alert – China. Issue 05, 2007 (1 May).

¹³³⁰ People's Daily Online: http://english.people.com.cn/200603/22/eng20060322_252583.html. March 22, 2006.

¹³³¹ Tsoi 2007.

These both took effect on 1st May 2007.¹³³²In addition to these, a new law called “Advertising Law on Public Interest” has been proposed. This law would add the amount of useful medicine advertising on TV in the form of “public service ads”.¹³³³

According to the new Standards and Measures, the following *five categories* of drugs are banned from advertising:

- narcotic drugs, psychotropic drugs, toxic drugs for medical use and radioactive drugs;
- medicinal preparations made by medical institutions;
- medicines specially needed by the army;
- medicines which have been specifically banned or prohibited from production, sale and use by SFDA; and
- medicines which have been granted approval for trial production.¹³³⁴

Use of *exaggerated expressions* and *unethical promotional phrases* is also banned. In order to ensure the safety of drugs, proper guidance should be given to their reasonable use. Medicine advertisements may not encourage excessive use of medicines. They may not contain the following content:

- sales promotion offering free medical treatment, free gifts, premiums, gifts or prizes in the form of medicines;
- “essential for every household” or similar expressions;
- “money back if ineffective”, “insured by insurance company” and other guarantees;
- information such as comparison with other drugs, ranking, recommendation and awards received.¹³³⁵

Further restrictions set by the new Standards to medicine advertising include the following:

- advertisements may not contain the name or image of army units or individual military personnel, or use military equipment or facilities for promotion purposes;
- advertisements may not target children or promote the medicine in the name of children;
- advertisements may not contain the name, address, contact information, and treatment methods of medical institutions; or information regarding free medical consultation, medical (hotline) inquiry, special outpatient service and other medical services offered by medical institutions.¹³³⁶

¹³³² Hong Kong Trade Development Council. www.tdctrade.com. Business Alert – China. Issue 05, 2007 (1 May).

¹³³³ People’s Daily Online: http://english.people.com.cn/200603/22/eng20060322_252583.html. March 22, 2006.

¹³³⁴ Hong Kong Trade Development Council. Key to Economy and Trade. Issue 05, 2007 (01 May)

¹³³⁵ Hong Kong Trade Development Council. Key to Economy and Trade. Issue 05, 2007 (01 May)

¹³³⁶ Hong Kong Trade Development Council. Key to Economy and Trade. Issue 05, 2007 (01 May)

In addition to banning certain types of medicine advertising, the new rules also created additional information requirements for both prescription medicines and over-the-counter medicines. Medicine advertisements must bear:

- the generic name of the medicine,
- warning statement,
- medicine advertising approval number,
- medicine production approval number, and
- name of the company producing or selling the medicine, and may not show the “helpline” or “helpline number” separately.

Since 2000, OTC and prescription medicines have been regulated separately. Encouraging patients to purchase OTC medicines for less serious diseases is considered beneficial as it reduces government medication expenditures and hospital visits.¹³³⁷ The warning statement for prescription medicine advertisements is: “This advertisement is intended only for medical and pharmaceutical professionals”. The warning statement for over-the-counter (OTC) medicine advertisements is: “To be purchased and used according to the specifications of the drug or as recommended by pharmacist.” *Prescription medicines may not be advertised directly to the public.* Like in Europe, they may only be advertised in designated medical and pharmaceutical journals. Non-prescription drug advertisements must bear *the OTC label*.¹³³⁸

Advertisements of medicines that claim to improve or boost sexual performance must be completely in line with the symptoms or indications shown in the approved drug specifications. Advertisements with this kind of content are banned from broadcast on TV or radio between 7 am and 10 pm.¹³³⁹

5.5 Claims in Medicine Marketing

Above (chapter 5.4.) we have discussed the general rules on medicinal advertising. Here we focus on efficacy and the rules on presenting the medicinal claim.

5.5.1 EU Rules on Medicinal Claims

5.5.1.1 Modern medicines¹³⁴⁰

A modern medicine (pharmaceutical, chemical medicine, synthetic medicine) must have a therapeutic (medical) indication. *The therapeutic indication is mandatory information* that must be included in an application for authorisation, more precisely in the Summary of Product Characteristics (SPC). This means that *medicines always bear a claim* stating a medical indication. The Summary of Product Characteristics sets out the scientifically agreed position of the medicinal product, which is distilled during the course of the

¹³³⁷ Wikipedia. Article on pharmaceutical industry in China.

¹³³⁸ Hong Kong Trade Development Council. Key to Economy and Trade. Issue 05, 2007 (01 May)

¹³³⁹ Hong Kong Trade Development Council. Key to Economy and Trade. Issue 05, 2007 (01 May)

¹³⁴⁰ Here we mean medicines that are not herbal or homeopathic medicines.

pre-market assessment process. The Summary of Product Characteristics, including the approved therapeutic indication(s), is the basis of information for health professionals on how to use the medicinal product safely and effectively, and it cannot be changed except with the approval of the originating competent authority. The label and the package leaflet are drawn up in accordance with the SPC.¹³⁴¹

The therapeutic indication(s) should be stated clearly and concisely and should define the target disease or condition distinguishing between:

- A) *treatment* (symptomatic, curative or modifying the evolution or progression of the disease) indication,
- B) *prevention* (primary or secondary¹³⁴²) indication, and
- C) *diagnostic* indication.

When appropriate, the indication should define the target population especially when restrictions to the patient populations apply.¹³⁴³

The basic principle is that by the information in the label and the package leaflet, patients should be fully and correctly informed about the medicine they are using. *There is only one case where the therapeutic indication is not allowed.* According to Directive 2001/83/EC¹³⁴⁴, “the competent authorities may decide that certain therapeutic indications shall not be mentioned in the package leaflet, where the dissemination of such information might have serious disadvantages for the patient”. This clause was introduced to avoid circumstances where a patient might not have been informed of the diagnosis (cancer, for instance) and would learn about it when reading the package leaflet of the medicine. This derogation from general principles should only be used in exceptional circumstances.¹³⁴⁵

5.5.1.2 Herbal Medicines

When discussing the efficacy of herbal medicines, we should briefly go back to the separation of foodstuffs and medicines discussed in chapter 3. Some herbal marketers intentionally blur the line between foodstuffs and medicines. Food supplements have a nutritional, not a medical use. They must not contain medicinal substances, medicinal plants or vitamins with medicinal effect. Many herbals classified as food supplements are in practice used if not to prevent a

¹³⁴¹ Notice to Applicants. A guideline on summary of product characteristics. October 2005. Included in The Rules Governing Medicinal Products in the European Union. Volume 2C. Page 1.

¹³⁴² We discussed different types of prevention in chapter 3.3. The difference between prevention and risk reduction separates foods from medicines. According to Wikipedia, primary prevention avoids the development of a disease, and secondary prevention prevents progression of a disease or the emergence of symptoms. For example, if a person has already had a heart attack, (s)he needs secondary prevention to prevent it happening again. Also the term ‘tertiary prevention’ is in use, but apparently activities that reduce the negative impact of the disease are in Europe classified as ‘treatment’.

¹³⁴³ Notice to Applicants. A guideline on summary of product characteristics. October 2005. Included in The Rules Governing Medicinal Products in the European Union Volume 2C Notice to Applicants. Page 4.

¹³⁴⁴ Article 59 (2).

¹³⁴⁵ Notice to Applicants. Guideline on the packaging information of medicinal products for human use authorised by the Community. March 2007. Included in The Rules governing Medicinal Products in the European Community. Page 9.

certain disease but at least to enhance health. The producers want to sell their products as foods because of the much simpler import, sales and marketing rules. But simultaneously, they want in their marketing to give the impression that the product acts like a medicinal product. Therefore, there are herbal products on the market that are sold as foods but still illegally marketed as medicines.¹³⁴⁶

As regards efficacy, herbal medicines are totally different from synthetic drugs. The *quality of the medicinal plant* is decisive to the quality of the products. Preparing herbal medicines is a bit like preparing wine: every year it is a bit different even if the plants are grown in the same place. Herbs grown in different countries have even bigger differences. In the package of the herbal medicinal product, the amount of the plant extract is given. This is called the therapeutic ingredient. Therapeutic ingredient does not, therefore, mean any single chemical substance like with synthetic medicines. The plant extract can contain hundreds of chemical compounds, and the amount of each chemical is not usually known.¹³⁴⁷

Medicinal plants can be used as such either fresh or dried. For some plants, all above ground parts can be used. For others, only leaves, seeds, flowers or roots are used. Plants or plant parts can be used to produce:

- herbal tea,
- simple extracts (tincturae) or
- extracts produced with more complex procedures (extracta).¹³⁴⁸

Herbal tea is produced like ordinary tea by infusing a dried medicinal plant in boiling water. Extracts are produced by using solvents that dissolve ingredients of the plant into the liquid, which is usually a mixture of water and alcohol. The goal is to dissolve as many medicinal ingredients as possible. The extract can be used either as such (tincture) or it can be concentrated by evaporating the solvent (extract). Extract reminds synthetic medicines because it is usually in form of pills, capsules or tablets. These are significantly stronger than tinctures. Some plant ingredients can also be removed in the process.¹³⁴⁹ The producers often standardise the product in relation to one chemical substance in the product, usually the most important therapeutic ingredient. This way the final product always contains the same amount of this one ingredient.¹³⁵⁰

In practise, herbal medicinal products are tablets, capsules, mixtures or enemas. They must contain only medicinal plants, not pharmaceuticals or synthetic vitamins.¹³⁵¹ Herbal medicines must apply for a Product License. The principal application procedure is the same as for chemical medicines. When marketing herbal medicinal products, the marketer must *adhere to the therapeutic use accepted by the authorities* and the product information presented in the Summary of Product Characteristics. The general rules of medicine marketing apply: marketing must not lure into excess use of herbs or be otherwise improper.¹³⁵²

¹³⁴⁶ Enkovaara 2002, 21.

¹³⁴⁷ Enkovaara 2002, 33.

¹³⁴⁸ Enkovaara 2002, 33.

¹³⁴⁹ Enkovaara 2002, 36.

¹³⁵⁰ Enkovaara 2002, 37.

¹³⁵¹ Enkovaara 2002, 22.

¹³⁵² Enkovaara 2002, 31.

Since 1986, established medicinal products do not have to go through new clinical tests. This means that a product license can be admitted based on scientific literature published on the substance. The literature must show that the substance has established medical use and that it has acknowledged efficiency and acceptable safety.¹³⁵³ According to directive 1999/83/EC¹³⁵⁴, a medicinal product, also a herbal medicinal product, has a record of well-established medicinal use if it has been used as a medicine in the EU territory for at least 10 years. In practice, applications for authorisation of herbal medicines are often based on established medicinal use, not clinical tests and trials¹³⁵⁵.

If someone wants to market an herbal medicine that does not have established medicinal use in Europe, he must complete clinical trials similar to those for synthetic medicines. Under the European Medicines Agency (EMA), there is a Committee on Herbal Medicines. The Committee was established in 2004, and it gives scientific opinions on herbal medicines. One of the basic guidelines concerning herbal medicines drafted by the EMA committees is the 2006 Guideline on Quality of Herbal Medicinal Products and Traditional Herbal Medicinal Products¹³⁵⁶.

5.5.1.3 Traditional Herbal Medicines

Traditional herbal medicines are a new European regulatory category created by Directive 2004/24/EC. It is a tailor-made category for products on which there is not enough scientific literature to make them well established in a sense that they could be authorised in the primary procedure for medicines. Traditional herbal medicines can be registered in a simplified procedure called ‘traditional-use registration’.

According to preamble 5) of the Directive 2004/24/EC, “the long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience”. According to Article 16(a)(e), the data on the traditional use of the medicinal product must be sufficient, in particular:

- the product must prove not to be harmful in the specified conditions of use, and
- the *pharmacological effects or efficacy* of the medicinal product must be *plausible* on the basis of long-standing use and experience.

This means that products categorised as traditional herbal medicines, require *no clinical data to show proof of efficacy*. The difference between a literature-based herbal medicine application and a traditional herbal medicine registration is that in the primary procedure, 10 years of established medicinal use is enough, and in the simplified procedure, 30 years of traditional use is enough. Established use means scientifically established through adequate published

¹³⁵³ Enkovaara 2002, 20.

¹³⁵⁴ Commission Directive 1999/83/EC of 8 September 1999 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products.

¹³⁵⁵ National Agency for Medicines web page at: <http://www.nam.fi/laaketeollisuus/rohdosvalmiste/kasvirohdosvalmiste/index.html>.

¹³⁵⁶ Available on EMA web page at: <http://www.ema.europa.eu/pdfs/human/qwp/281900en.pdf>.

data. The borderline between established use and traditional use still remains unclear, and EMEA guidelines are expected on the subject.

Because efficacy of traditional herbal medicines is not based on scientific trials, there is certain mandatory information that must be given to the consumer. There is an obligation to include in the labelling, the package leaflet and in any advertising the information that the product is a traditional herbal medicinal product and that *the efficacy has not been clinically proven but relies exclusively on long-term use and experience*; and that the user should consult a doctor or a qualified medical practitioner if the symptoms persist during the use of the medicinal product.

Compared to chemical medicines, there is still a relative lack of rigorous clinical trials on herbals. The efficacy of herbal medicines has been tested in hundreds of clinical trials, but this volume of data is still small considering the thousands of plants that are used as medicines. Studies have shown that herbal medicines might often have fewer serious side effects compared to pharmaceuticals. They might also offer just as effective remedies with lower cost. However, the evidence on these benefits is incomplete.¹³⁵⁷ This is why the legislator has had to settle with the above- described approach, where the product can be marketed based on history of use, but the consumer has to be informed of the lack of evidence. *The decision on whether to trust a traditional herbal medicinal product is on the consumer.*

The lack of trials is mostly due to the fact that the herbal industry is small and can rarely afford the considerable expense of a clinical trial. Public funds are not often dedicated to research of herbal medicines. The EU directive harmonising the registration of herbal medicines did not offer any incentives for companies to invest further into research. Research is needed to enable knowledge-based use of herbal medicine.¹³⁵⁸ At the moment, a consumer must rely more on faith and less on facts when using herbals. The lack of complete evidence is possibly holding back the optimal use of herbals. There are arguments against ‘history of use’ as a ground for authorisation. Historically, there have been long-standing traditions of treatments later proven to be ineffective.

5.5.1.4 Homeopathic Medicines

Homeopathic products can be approved either in the primary authorisation procedure for medicines according to Article 16(1) or their own simplified registration procedure according to Article 14(1) of the Medicinal Products Directive 2001/83/EC. In practice, the simplified registration scheme “appears to be applicable to the majority of homeopathic medicinal products”¹³⁵⁹. The primary procedure is problematic as regards Mutual Recognition. In case of disagreement between Member States, referrals to the EMEA Committee on Human Medicinal Products do not apply to homeopathic medicinal products.¹³⁶⁰

According to Article 14(3) of the Medicinal Products Directive, *proof of therapeutic efficacy is not required* of the homeopathic products registered according to the simplified procedure. Correspondingly, the labelling of those products shall bear the following information:

¹³⁵⁷ Ernst 2003.

¹³⁵⁸ Ernst 2003.

¹³⁵⁹ Report on EMEA Workshop on Homeopathic Medicinal Products. London, 27th October 2006. Page 6.

¹³⁶⁰ Report on EMEA Workshop on Homeopathic Medicinal Products. London, 27th October 2006. Page 7.

“homeopathic medicinal product without approved therapeutic indications”.¹³⁶¹ Article 15 lists the information needed in the simplified procedure. This information includes *bibliographical data* concerning the product’s homeopathic nature¹³⁶². This means homeopathic use of the product must be presented, for instance, on the basis of the literature.¹³⁶³

The rules of the simplified procedure indicate that a consumer must get the product (s) he orders, but efficacy is not guaranteed. A consumer may or may not believe that because the product has been used in homeopathy for condition X, it is effective for condition X. As discussed above in chapter 4, the Member States may or may not establish the simplified procedure. This had led to an unharmonised state, which creates obstacles to practitioners of homeopathy. The dispute on whether homeopathy is actually effective goes on worldwide. *The Lancet* attacked homeopathy in 2005 stating that a review of 110 trials found no convincing evidence the treatment worked any better than a placebo¹³⁶⁴.

5.5.2 Chinese Rules on Medicinal Claims

The rules on efficacy and marketing are basically the same for modern and traditional medicines in China. Traditional Chinese Medicine (TCM) remains a recognised and valued source of treatment¹³⁶⁵. The Chinese government has supported the development of both traditional Chinese medicine and Western medicine in China. As described above in chapter 4, the Chinese intend to be a global leader in bringing herbal medicine into the 21st century by establishing modern standards.

¹³⁶¹ If homeopathic medicinal products are placed on the market with therapeutic indications or in a form, which may present risks that must be balanced against the desired therapeutic effect, the usual rules governing the authorisation to market medicinal products are applied. This means that in these cases, the same market authorisation and labelling rules apply as to immunological medicinal products.

¹³⁶² Article 15: “An application for special, simplified registration may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned:

- scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered,
- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography,
- manufacture and control file for each pharmaceutical form and a description of the method of dilution and potentiation,
- manufacturing authorisation for the medicinal product concerned,
- copies of any registrations or authorisations obtained for the same medicinal product in other Member States,
- one or more specimens or mock-ups of the outer packaging and the immediate packaging of the medicinal products to be registered,
- data concerning the stability of the medicinal product.”

¹³⁶³ National Agency for Medicines web page at: http://www.nam.fi/english/pharma_industry/herbal_remedy/homeopathic/index.html.

¹³⁶⁴ BBC News 26 August 2005.

¹³⁶⁵ China-Britain Business Council. China-Britain Business Review Archive.

According to the new Chinese Standards and Measures on medicine advertising (2007), claims on the curative effects of medicines in advertisements must be scientific and accurate and may not contain any of the following content:

- unscientific assertion or guarantee of efficacy;
- claims of curative rate or efficiency;
- comparison of effects and safety with other medicines;
- explicit or implicit suggestion that the drug can heal all diseases and is good for all symptoms in contravention of the rules of science;
- suggestion that the medicine is “safe with no toxic side effect” or has “very little toxic side effect”;
- for proprietary Chinese medicine, explicit or implicit suggestion that it is “natural” and guaranteed safe;
- explicit or implicit suggestion that the medicine is essential for normal daily life and for the treatment of diseases;
- explicit or implicit suggestion that the medicine can help one cope with the tension of modern life, studies or examination, and can help boost academic performance, energy, competitiveness, height and intelligence;
- other unscientific terms or suggestions such as “the latest technology”, “state-of-the-art science” and “the most advanced methods of preparation”.

The rules on therapeutic claims are thus the same for modern and traditional medicines, with no special categories for medicines without proven therapeutic efficacy. However, the scientific criteria for efficacy are not yet established.

5.6 Food and Medicine Marketing: Conclusions

As with safety, there are no particular rules on the marketing of functional foods. Again, this is because there is no legal category of functional foods. General marketing rules apply to the marketing of functional foods. Marketing must be decent and truthful. In addition, food marketing or medicine marketing rules apply. As with safety, marketing rules of foodstuffs vs. medicines vary considerably. The main difference is that foods are allowed to bear health claims, and medicines are to have medicinal claims.

General rules on food marketing are largely the same within the EU and in China. The mandatory ingredient list will advise the consumer on what is in the product, and misleading advertising is prohibited. China has recently introduced legislation on nutrition labelling and nutrition claims, which is comparable to its European counterpart. Guideline daily amounts (GDA) are used as a guide for consumer.

Health claims are allowed both in the EU and in China. In China, a category of health foods has been created. Health foods are the only foods that can bear health claims, and no foods can bear medicinal claims. The category of health foods is suitable for all foods with health effects, including normal foods, fortified foods and food supplements. In Europe, normal foods, dietetic foods and food supplements can bear health claims. The EFSA and the Commission have defined the borderlines of nutrition claims and the two separate types of health claims:

function claims and disease risk reduction claims. The separation between disease risk reduction and disease prevention is the separation between foodstuffs and medicines.

The general rules on medicine marketing are also largely the same in the EU and China. The basic law guarantees that consumers receive enough information on the use of the medicine, on its therapeutic effects, side effects, precautions etc. The law also prohibits typically unethical marketing methods such as targeting children. The Chinese government has recently improved laws on medicine marketing to tackle the serious problems that have occurred.

With regard to efficacy, which is closely related to the medicinal claim, the required scientific proof varies according to the type of medicinal product. In Europe, legislators have created separate categories of traditional herbal medicines and homeopathic medicines, for which no scientific proof of efficacy needs to be presented. On the other hand, no therapeutic claims can be presented for these products. This means the legislator has left it up to the consumer to decide whether to trust the product based on tradition only. For regular medicines, the requirements for scientific tests and clinical trials are very strict, and the EMEA evaluates the evidence on behalf of the consumer.

In China, foods have always been used for medicinal purposes. Medicinal products are divided into two: traditional Chinese medicines and modern medicines. Compared to Europe, China is putting more emphasis on traditional medicines and developing them side-by-side with modern medicines. China is building a science-based approach and modern legislation on traditional medicines. In the future, efficacy of traditional medicines will be evaluated according to special legislation.

The laws on marketing of foodstuffs and medicines are often disobeyed both in China and in Europe. Illegal marketing practices are common regarding health foods, dietetic foods and food supplements. These are often marketed as medicines. In China, there have been serious cases of fake medicines. With health-related products, certain factors lead to misleading marketing: Consumers are ignorant compared to businesses, consumers cannot immediately determine if the product is effective or not, and health is so important to consumers that they are willing to pay for it even if the result is uncertain. This means there are lucrative earnings available for swindlers. It is a challenging job for legislators to make deception unprofitable.

6 CASE: THREE CHINESE BERRIES

6.1 Case Introduction

In this chapter, we draw conclusions on the European and Chinese legal systems from an entrepreneur's perspective. For this purpose, a case concerning fictional health-enhancing products and their legal status is presented. This means investigating how the legislation works in the situation of *three Chinese plants* aimed at fighting *the metabolic syndrome*.

The chosen plants are:

- 1) Hawthorn fruit (*Crataegus pinnatifida*, Chinese hawthorn)
- 2) Emblic leafflower fruit (*Phyllanthus emblica*), and
- 3) Chinese wolfberry fruit (*Lycium barbarum* L.).



These berries have qualities that make them promising raw materials for functional foods. We are interested in how these plants are/would be legally evaluated in EU and in China. Our hypothetical goal is to produce functional foods utilising the health-enhancing properties of these three berries, and to legally sell the products to consumers.

The important legal questions are:

- A) Which are the applicable rules?
- B) Is it possible to sell the products as foods and/or medicines?
- C) If foods, will the products be classified as novel foods?
- D) If novel foods, which are the requirements for authorisation?
- E) Which will be the marketing claims available?

Exotic fruits and berries have shot to popularity in the last couple of years, particularly because of their antioxidants and vitamin C. The food industry calls this the 'superfruit' trend.

Food and beverage manufacturers are developing products to reply to consumer demand for wolfberries, cranberries, noni, and blackberries for example.¹³⁶⁶

6.2 Scientific Background

6.2.1 Target Diseases

The *metabolic syndrome* is a condition where a person is overweight and in risk of getting cardiovascular disease and diabetes. This means the person has high blood pressure, low level of (good) HDL cholesterol, high level of (bad) LDL cholesterol, insulin resistance and/or glucose intolerance. The condition is called metabolic syndrome, because the risk of contracting heart trouble and the risk of getting diabetes are often associated with the same persons. The lipid (fat) metabolism and the glucose (sugar) metabolism are closely connected, and both are connected to obesity. *By treating metabolic syndrome it is possible to prevent type 2 diabetes and cardiovascular disease.*

Researchers link the rise in metabolic syndrome to growing affluence, changing lifestyles and growing urbanisation¹³⁶⁷. The syndrome is common in middle-aged and older persons. According to Hu et al., the overall prevalence of the metabolic syndrome in non-diabetic adult Europeans is 15%¹³⁶⁸. The WHO estimates that metabolic syndrome is present in 7–36% of European men and 5–22% of women aged 40–55 years¹³⁶⁹. According to a 2005 study, 13.7 % of Chinese adults has metabolic syndrome¹³⁷⁰. According to He et al., the prevalence of metabolic syndrome is 46% in Beijing elderly people¹³⁷¹, 35% in men, 54 in women^{1372, 1373}

These figures are important as they point out that the syndrome causes a lot of human suffering and huge economic losses. What is interesting to us is that obesity, cardiovascular disease, and diabetes are largely *nutrition problems*.¹³⁷⁴ The metabolic syndrome can often be prevented and/or treated by diet, where functional foods can be one part of dietary therapy.

Obesity is the basic culprit for many health problems. Obesity increases the risk of cardiovascular disease and type 2 diabetes.¹³⁷⁵ In Europe, around half of the adult population

¹³⁶⁶ Nutraingredients.com Europe. News Headlines 18/06/2007.

¹³⁶⁷ Functional Ingredients September 2005 China News.

¹³⁶⁸ Prevalence of the Metabolic Syndrome and Its Relation to All-Cause and Cardiovascular Mortality in Nondiabetic European Men and Women. Gang et al. 2004.

¹³⁶⁹ Tonkin 2004.

¹³⁷⁰ Functional Ingredients September 2005 China News.

¹³⁷¹ 60 to 95 years.

¹³⁷² These figures are based on the International Diabetes Foundation definition of metabolic syndrome. Yao et al. 2006.

¹³⁷³ Apparently the situation is worse in the U.S. Around 25 % of Americans have the metabolic syndrome. Over 40 % of Americans over 60 have it. Metabolic Syndrome Institute web page at: http://www.metabolic-syndrome-institute.org/medical_information/mets_epidemic

¹³⁷⁴ Chai 2004.

¹³⁷⁵ In Europe, a person is considered overweight, if BMI (body mass index) is at least 25, and obese, if BMI is at least 30. The Chinese use different cut-off points for overweight and obesity. A person is considered overweight, if BMI is at least 24, and obese if BMI reaches 28.

is overweight¹³⁷⁶. China faces the dual problem of malnutrition and obesity. Chronic diseases associated to obesity are increasing rapidly in China.¹³⁷⁷ 20.7 % of Chinese were overweight in 1997¹³⁷⁸. According to a 2005 study, some 18 million adults in China were obese, and 137 million were overweight¹³⁷⁹. *Abdominal fat* is particularly dangerous.¹³⁸⁰ Abdominal obesity is associated with insulin resistance and predicts the onset of type 2 diabetes. Abdominal obesity also predicts coronary artery disease, more directly than BMI (body mass index).¹³⁸¹

Diabetes is a condition where the body cannot handle glucose (sugar). Hyperglycaemia (too much sugar in the blood) appears when pancreatic beta cells can no longer compensate insulin-resistance by increasing insulin release.¹³⁸² Type 1 and type 2 diabetes have different causes and population distributions.¹³⁸³ Type 1 diabetes cannot be prevented. Type 1 diabetes was traditionally called juvenile diabetes, as most children's diabetes is type 1. Here we only discuss type 2 diabetes, as it is most interesting regarding functional foods. Changes in lifestyle can delay or prevent onset of type 2 diabetes. Risk factors for type 2 diabetes include, among others, obesity, low level of HDL, and high level of triglycerides in the blood.

A worldwide diabetes epidemic is occurring. Around 8% of Europeans and adult Americans have diabetes¹³⁸⁴. The cause of death for diabetics is often cardiovascular disease, for example a stroke.¹³⁸⁵ There is no cure for diabetes. Type 1 diabetes is always treated with insulin injections, plus diet. Some people with type 2 diabetes can manage their disease with diet and exercise alone, others require medicinal treatment. *Diet is important for both prevention and treatment of type 2 diabetes*. Goals of nutritional therapy are: control of blood sugar and blood lipid levels, control of hypertension, weight loss, and improving general health. Nutritional therapy is thus similar in cases of diabetes and heart disease.

In nutritional therapy, the terms glycemic index and glycemic load are important. *Glycemic index* ranks foods on how they affect our blood glucose levels.¹³⁸⁶ Different carbohydrates have different glycemic responses, i.e., they have different effects on blood sugar levels. *Glycemic load* of a serving of food is glycemic index (%) multiplied by grams of carbohydrate per

¹³⁷⁶ International Obesity Task Force web page at: http://www.iotf.org/database/documents/EUPresentationGraphNov06_004.ppt#1.

¹³⁷⁷ Chai 2004.

¹³⁷⁸ Chai 2004.

¹³⁷⁹ Functional Ingredients September 2005 China News.

¹³⁸⁰ To avoid risks associated with excess body fat, waist circumvention should not exceed 80 cm for female and 85 cm for male population.

¹³⁸¹ Metabolic syndrome institute web page at: http://www.metabolic-syndrome-institute.org/medical_information/definition.

¹³⁸² Metabolic syndrome institute web page at: http://www.metabolic-syndrome-institute.org/medical_information/definition.

¹³⁸³ In addition, there is gestational diabetes, which occurs during pregnancy and typically resolves when the baby is born. Metabolic syndrome institute web page at: <http://www.diabetes.org/gestational-diabetes.jsp>.

¹³⁸⁴ British Heart Foundation Statistics Website at: <http://www.heartstats.org/datapage.asp?id=4529>.

¹³⁸⁵ Metabolic syndrome institute web page at: http://www.metabolic-syndrome-institute.org/medical_information/definition.

¹³⁸⁶ Glycemic index is the area under the curve of blood glucose produced by an amount of carbohydrate in a food, relative to the area produced by the same amount of carbohydrate from a standard source (usually white bread or glucose). This means products containing carbohydrates are compared to a product that affects the blood sugar levels the most.

servicing. Epidemiological studies suggest that glycemic index and glycemic load are associated with increased risk of type 2 diabetes and cardiovascular disease. High-glycemic-load diets could increase risk of type 2 diabetes by increasing insulin demand, which could lead to beta cell exhaustion and glucose intolerance. These diets can also make the body produce counter-regulatory hormones which would increase insulin resistance, insulin demand and glucose intolerance. These mechanisms would create diabetes.

Oral medicines used to treat type 2 diabetes function by increasing insulin production, decreasing blood glucose or enhancing the body's ability to use its own insulin more effectively. A drug called metformin enhances insulin sensitivity.¹³⁸⁷ Thiazolidinediones are also insulin sensitising, and may improve insulin resistance.¹³⁸⁸

Cardiovascular diseases represent today the principal cause of mortality in developed countries. Heart disease is the leading cause of death for American, European, and Chinese adults¹³⁸⁹. The WHO presumes that CVD will become the primary cause of death worldwide by the year 2020. Prevalence of hypertension among Beijing residents aged 15–69 was 24.8% in 2001, and prevalence of coronary heart disease 7.22%. Of Beijing residents, 2.14% had had a stroke. In Shanghai, the pattern is similar.¹³⁹⁰ Consumption of animal-based products per capita has increased rapidly in China. It has tripled since the 60's.¹³⁹¹ Consumption of fat and meat continues to increase among Chinese urban citizens.¹³⁹²

The cardiovascular system is made up of the heart and blood vessels. Cardiovascular diseases (CVD) include coronary heart disease (coronary artery disease, ischemic heart disease), stroke (angina pectoris, heart attack), hypertension, and rheumatic heart disease (arrhythmia). Causes of cardiovascular disease are multiple and many lifestyle factors are related to the risk of CVD. Risk factors for cardiovascular disease are, among other things, hyperlipidemia, hypertension¹³⁹³, obesity and diabetes. Hyperlipidemia means excess of certain unbeneficial fats in the blood: LDL cholesterol¹³⁹⁴, triglycerides and phospholipids. Hypertension is defined as high blood pressure.

Several cardiovascular disease risk factors can be affected with diet. Goals of cardiovascular disease nutritional therapy are: to prevent obesity and type 2 diabetes, and to

¹³⁸⁷ Metabolic syndrome institute web page at: http://www.metabolic-syndrome-institute.org/medical_information/prevention_and_treatment.

¹³⁸⁸ Metabolic syndrome institute web page at: http://www.metabolic-syndrome-institute.org/medical_information/prevention_and_treatment.

¹³⁸⁹ Functional Ingredients September 2005 China News.

¹³⁹⁰ Chai 2004.

¹³⁹¹ Chai 2004.

¹³⁹² Chinese disease patterns show different characteristics in urban vs. rural areas. The transition in urban areas from communicable to non-communicable diseases is almost complete. Heart and brain vascular diseases, cancer and diabetes are increasing rapidly. In rural areas, communicable, endemic diseases such as tuberculosis are still not under control. Chai 2004.

¹³⁹³ Blood pressure is high if systolic pressure is at least 140 mmHg and diastolic pressure at least 90 mmHg.

¹³⁹⁴ Excess of blood cholesterol is called hypercholesterolemia. There are two main types of blood cholesterol: LDL and HDL. LDL (low density lipoprotein) is 'bad cholesterol' and related to CVD risk. HDL (high density lipoprotein) is 'good cholesterol' and inversely related to CVD risk. Reducing serum LDL cholesterol and increasing HDL cholesterol decreases risk of CVD. This is widely established.

maintain optimal levels of lipid profiles and blood pressure.¹³⁹⁵ Medicinal products to tackle dyslipidaemia (wrong kind of fat in the blood) include statins and fibrates. Statins act on LDL cholesterol, and fibrates act on HDL cholesterol and triglycerides¹³⁹⁶. Hypertension is treated with medicines such as diuretics, alpha blockers, beta blockers, calcium channel blockers, angiotensin receptor blockers, ACE inhibitors, sympatholytics, and vasodilators¹³⁹⁷.

6.2.2 Use of the Berries in Traditional Chinese Medicine

The medicinal use of hawthorn has a long history.¹³⁹⁸ In ancient times, the Chinese herbalists mainly used dried fruits of hawthorn to improve digestion. For the past thirty years, the use of hawthorn as a strengthener of the cardiovascular system has been noted and adopted by Chinese herbalists. Western applications of hawthorn have been verified by Chinese researchers and added to lists of hawthorn applications in Chinese medicine. There are now several hawthorn products on the market for strengthening heart function, lowering blood lipids, and dilating blood vessels to promote blood circulation.¹³⁹⁹

According to “The Essentials of Traditional Chinese Herbal Medicine”, hawthorn fruit (*Fructus Crataegi*, Shanzha) can promote blood circulation and release blood stasis¹⁴⁰⁰. Active components include organic acids such as crataegic acid, citric acid, and caffeic acid, flavonoids such as vitexin and quercetin, and vitamins such as vitamin C, riboflavin, and carotenes. Hawthorn flavonoids can increase blood flow in coronary blood vessels and lower blood pressure. Hawthorn fruit can also increase serum HDL cholesterol and reduce LDL cholesterol, and prevent atherosclerosis. For cardiovascular diseases such as hypertension, hyperlipidemia and coronary heart disease, hawthorn fruit is used as syrup, tablet, instant power and tincture. Average dosage is 10-15grams of raw or fried fruit; a large dosage is 30grams. A warning goes as follows: “Intake of an extra-large dosage of hawthorn may produce a sedative effect and inhibit respiration, although the drug is of low toxicity.”¹⁴⁰¹

Chinese wolfberries, also known as Goji berries, come from the *Lycium barbarum* plant, a vine that grows in China, Tibet and other areas of Asia. Wolfberry fruit (*Fructus Lycii*, Gouqizi) can, according to “The Essentials of Traditional Chinese Herbal Medicine”, treat

¹³⁹⁵ This means LDL 3.5-5 mmol/l with no specific goal on HDL cholesterol. Systolic blood pressure should be under 120 mmHg and diastolic blood pressure under 80 mmHg.

¹³⁹⁶ According to Taskinen, fibrates seem to be the optimal drug for correcting dyslipidaemia in patients with the metabolic syndrome *who have low LDL-cholesterol*. According to her, the management of these subjects is in clinical practice commonly neglected despite their increased risk of cardiovascular disease. Metabolic syndrome institute web page at: http://www.metabolic-syndrome-institute.org/medical_information/expert_point_of_view/taskinen.

¹³⁹⁷ Messmer 2006.

¹³⁹⁸ Food use of hawthorn is also important. Hawthorn fruits are in China used as a food to make many kinds of snacks, for example haw flakes, which are sold also in all the large cities in the U.S. The fruits, which are called *shānzhā* in Chinese, are also used to produce jams, jellies, juices, tea, wine, etc. Wikipedia. Article on hawthorn. <http://en.wikipedia.org/wiki/Crataegus>.

¹³⁹⁹ Dharmananda.

¹⁴⁰⁰ The Essentials of Traditional Chinese Herbal Medicine 2003, 126. Another important indication is digestion trouble. Hawthorn can promote digestion and release stagnation of food.

¹⁴⁰¹ The Essentials of Traditional Chinese Herbal Medicine 2003, 126-127.

“diabetes mellitus with endogenous heat due to deficiency of *yin*”. For this purpose, wolfberry fruit is combined with rehmannia, figwort root (*Radix Scrophulariae*, Xuanshen), Chinese yam, milkvetch root and magnoliavine fruit (*Fructus Schisandrae*, Wuweizi). It is stated that wolfberry fruit can apparently and persistently reduce blood sugar and lower blood pressure. Normal dosage is 5-10 grams of berries. A warning goes as follows: “Wolfberry fruit should not be prescribed for patients with diarrhoea due to deficiency of the spleen, because it can replenish *yin* and moisten dryness.”¹⁴⁰²

Hawthorn and Chinese wolfberry are mentioned in every common book on traditional Chinese medicine. According to Cai, hawthorn is used to lower blood pressure and blood cholesterol¹⁴⁰³, wolfberry fruit to lower blood pressure and blood sugar¹⁴⁰⁴, and wolfberry root to treat high cholesterol¹⁴⁰⁵. According to Zhao, hawthorn fruit is used to lower blood pressure¹⁴⁰⁶, and wolfberry fruit to treat diabetes¹⁴⁰⁷. According to Hou et al., hawthorn fruit is used “to promote blood circulation and disperse blood stasis, lower blood pressure and the level of blood lipids¹⁴⁰⁸”, and wolfberry to treat diabetes¹⁴⁰⁹. Hawthorn is also used to treat obesity¹⁴¹⁰.

Emblc leafflower is apparently not among the most commonly used medicinal plants, as the general Chinese books on traditional Chinese medicine do not recognise the plant. This is probably because roots of its medical use are in ancient India, where it was respected as “Saint fruit”¹⁴¹¹ and because it was typically used by the Tibetan minority of China. Even today the fruit is most popular in India. The plant is, however, recorded in the Chinese pharmacopoeia. It is used, among other things, to cure “internal heat”, “blood heat”, “blood disease”, and high blood pressure.¹⁴¹²

6.2.3 Scientific Evidence on the Berries

It was stated above that hawthorn, emblic leafflower, and barbary wolfberry have potential for use in functional foods. This is not just because they are part of the above-mentioned superfruit trend, but because they actually have scientifically proven beneficial effects on risk factors of cardiovascular diseases, type 2 diabetes, and the metabolic syndrome. The effects are mainly due to flavonoids and triterpene acids in hawthorn, polysaccharides and alkaloids in barbary wolfberry, and vitamin C and tannoids in emblic leafflower. We will not list all the available scientific research on the berries, but refer to some of the latest studies that might be relevant in supporting health claims on our functional foods.

Hawthorn fruit has been found to have:

¹⁴⁰² The Essentials of Traditional Chinese Herbal Medicine 2003, 254-255.

¹⁴⁰³ Cai 1993, 107.

¹⁴⁰⁴ Cai 1993, 102.

¹⁴⁰⁵ Cai 1993, 71.

¹⁴⁰⁶ Zhao 1996, 85.

¹⁴⁰⁷ Zhao 1996, 79.

¹⁴⁰⁸ Hou 1994, 61.

¹⁴⁰⁹ Hou 1994, 71.

¹⁴¹⁰ Hou 1994, 142.

¹⁴¹¹ Yalin Health company web page at: <http://www.yalin-health.com/en/info/index.asp?id=5>.

¹⁴¹² Yalin Health company web page at: <http://www.yalin-health.com/en/info/index.asp?id=5>.

- hypolipidemic activity¹⁴¹³,
- positive effects on arteries and coronary flow¹⁴¹⁴,
- positive effects on blood pressure¹⁴¹⁵, and
- antioxidant activity¹⁴¹⁶.

Emblic leafflower fruit has been found to have:

- hypoglycemic activity¹⁴¹⁷,
- hypolipidemic activity¹⁴¹⁸,
- cardioprotective effects¹⁴¹⁹, and
- antioxidant activity¹⁴²⁰.

Chinese wolfberry fruit has been found to have:

- hypoglycemic activity¹⁴²¹,
- hypolipidemic activity¹⁴²², and
- antioxidant activity^{1423, 1424}.

Hypoglycaemic is something that lowers the level of sugars in the blood. Something that is hypolipidemic lowers the level of lipids. Antioxidants protect cells from damage. The berries could be used in functional foods as such (dried), or their active ingredients could be captured. Some of the more technological options for functional foods are:

- oils,
- “phenolic fractions”, and
- glycoconjugates (barbary wolfberry).

6.3 Which Rules to Follow?

In chapter 2, we have discussed the European and Chinese legal systems on foodstuffs and medicines from regulators to implementing agencies. Norms on several levels and of several types are relevant to legal evaluation of our functional food products.

¹⁴¹³ Xiong et al. 2004. Chen et al. 2002.

¹⁴¹⁴ Pittler et al. 2008. See also Cai et al. 1999, which was on leaf extract, not berries.

¹⁴¹⁵ Walker et al. 2006.

¹⁴¹⁶ Gong – Wang 2005. Zhang et al. 2001.

¹⁴¹⁷ Suryanarayana et al. 2007.

¹⁴¹⁸ Anila – Vijayalakshmi 2002. Anila – Vijayalakshmi 2003. Augusti et al. 2001.

¹⁴¹⁹ Liu et al. 2003. Liu et al. 2005.

¹⁴²⁰ Kaur – Kapoor 2002. Bajpai et al. 2005.

¹⁴²¹ Tian – Wang 2005.

¹⁴²² Jiang et al. 2007. Ma et al. 2005.

¹⁴²³ Xin et al. 2007. Wu et al. 2004.

¹⁴²⁴ Luo et al. 2004. relates to all of these actions.

6.3.1 International Agreements and Cases

Usually, global agreements and standards like Codex Alimentarius agreements have their effects on private parties through the member states by their legislative organs and enforcement organs. The European Court of Justice has stated that WTO agreements are not intended to confer rights on individuals. It has still found some situations where private parties are allowed to rely on WTO agreements as interpreted by the WTO Dispute Settlement Body. According to Pere, these situations are limited in applicability and leave important gaps to rights of private persons. Although WTO law is binding, it seems to lack effective remedies. A company cannot necessarily receive any compensation for damage suffered due to a Member State not complying with their WTO obligations or as a result of countermeasures to such WTO-illegal action.¹⁴²⁵

The relationship between WTO law and Chinese law is similar: if China has failed to meet a WTO obligation, a private company can probably not resort to WTO law against the Chinese government. When China adjoined the WTO, there was academic debate on whether PRC courts should directly apply WTO agreements¹⁴²⁶. According to Jie, there are no clear rules on the hierarchy between Chinese laws and treaties. The ambiguous hierarchy is deliberate, leaving room for discretion for Chinese legislators and courts.¹⁴²⁷

6.3.2 EU

When in Europe, one must first look into the Community level Regulations and Directives. With foodstuffs, the General Food Regulation gives general principles on producer responsibilities. Concerning functional foods, the Novel Food Regulation and the Regulation on Nutrition and Health Claims are often relevant. With medicines, the Medicinal Products Directive is the most important one. The directive was recently amended with regard to traditional herbal medicinal products.

Secondly, there are laws by Member State parliaments, and lower level decrees and decisions by Member State ministries. In Finland for example, the Food Act is very similar to the European General Food Regulation. The EU principles such as the precautionary principle are transferred into Member State laws with little room for discretion. The European and national laws may be defined as ‘hard law’, as they have their base in EU Treaties and Member State constitutions. Hard law is enforceable by European and Member State courts. If rules are not followed, the functional food product can be taken off the market or have its marketing claim prohibited. Also civil liability and criminal sanctions might follow.

So-called ‘soft law’ is important in connection with foodstuffs and medicines. With foodstuffs, one must follow guidelines by the European Commission, the EFSA, and national food authorities. Concerning novel foods, the Commission Recommendation includes detailed requirements of the application procedure. On health claims, the EFSA has produced

¹⁴²⁵ Pere 2005, 85. We will not go further into analysing the direct effect of WTO law to private persons. See Pere 2005 on European case law thereof.

¹⁴²⁶ Hu 2000, 104.

¹⁴²⁷ Jie 2008, 108.

guidelines for example on how to draft applications¹⁴²⁸. Of national soft law, the Finnish guides on health claims and food supplements by the Finnish Food Safety Agency might be relevant for our purposes. With medicines, the “Notice to Applicants” by the Commission and scientific guidelines by the EMEA are important sources of law.

Legally, guidelines are not binding. However, if an applicant chooses not to follow a guideline, this decision must be explained and justified in the dossier. The courts might give administrative soft law the weight similar to hard law norms. The problem of reliability of soft law is relevant also to a lawyer’s responsibility towards his client. Normally, a lawyer cannot be sued for negligence if he bases his advice on soft law. If the soft law cannot ultimately be enforced, the client cannot sue the maker of the soft law, either. This is because the producer of soft law can revert to the fact that soft law is non-binding guidance only.

Scholars of legal theory have listed attributes of soft law that add weight to it. The evaluation depends on:

- how the regulation is created (quasi-democracy, stakeholder involvement),
- formal recognition of the regulation (referral to soft law in hard law),
- degree of utilisation of the regulation (the more used, the more binding), and
- moral acceptability (the more compatible with current values, the more binding).¹⁴²⁹

Based on these criteria, typical European soft law (such as EFSA and EMEA advice on how to draft applications) can be regarded as fairly binding.

To keep up the good reputation of the industry, and to be respectable among other industry players, one should also have a look at self-regulation guidelines. There are guidelines by the European food industry association (CIAA) and the European Health Product Manufacturers.

One could also decide not to follow the rules. All EU Member States foresee fines and/or imprisonment as criminal penalties for the sale of unsafe products, for example unhygienic foods or counterfeit medicines. Also misleading advertising, for example presenting fake health claims, is a crime. In civil proceedings, damages may be imposed on consumers, business partners, and sometimes also to competitors.

6.3.3 China

In China, the food and medicine law consists of certain basic laws given by the National People’s Congress or the State Council, and several supplementing pieces of regulation given by the Ministry of Health or the State Food and Drug Administration (SFDA). Compared to the European system, Chinese laws are more fragmented, each law covering one aspect of the foodstuff and medicine business. These separate pieces of regulation must be read together.

If we decide to sell our berry products as foodstuffs, the general Food Safety Law and particularly the Health Food Regulation are most relevant to us. The original Health Food Regulation of 1996 has been supplemented by over 20 Notifications by the Ministry of Health

¹⁴²⁸ See EFSA pre-submission health claim guidance for applicants 2007, and EFSA scientific and technical health claim guidance for applicants 2007.

¹⁴²⁹ Koulu 2009, 132.

and the State Food and Drug Administration. These govern good manufacturing practice, the application procedure, labelling, and advertising of health foods. In the future, health food regulations will be consolidated in a single piece of law.

The Chinese Regulation on Novel Foods will possibly be relevant if we use a raw material that has not traditionally been used in China. The new Novel Food Regulation came into force in December 2007, replacing the original regulation dating from 1991. However, health foods and novel foods are separate legal categories in China, and novel foods cannot bear health claims. As we probably want to market our functional foods as health-enhancing, we will have to register them as health foods. In this case, both the safety and efficacy of the product will be examined in the health food procedure, and the novel food procedure does not apply.

If we decide to sell berry products as traditional medicines, the rules of the general Medicine Administration Law apply. New legislation particularly on traditional medicines is impending. It will include precise rules on safety and efficacy of traditional medicines.

Besides national rules, there are also local rules by cities and provinces. In Hong Kong for example, foodstuffs and medicines are mainly regulated together in Part V (Food and Drugs) of the Public Health and Municipal Services Ordinance (Cap. 132)¹⁴³⁰. Sometimes local rules contradict with national rules in hygiene issues, for example. In this case, it might be advisable to abide by the stricter rules.

6.4 Foodstuffs or Medicines?

Based on the evidence above, we assume the three berries (or their fragments) to have a scientific base for use in health-enhancing products in EU and China. These products would be aimed at fighting the metabolic syndrome. First, we must consider whether these products would legally be treated as foods or medicines. In chapter 3, we have discussed the European and Chinese rules on categorisation.

6.4.1 EU

6.4.1.1 *The Choice between the Two Categories*

In EU law, there is no definition or category for functional foods. The categories of foodstuffs and medicines have traditionally been distinct. Whether the product is a food or a medicine is an important question as there are two different sets of law: one for foods and another for medicines. The most important difference between foodstuffs and medicines is that a risk/benefit ratio is applied to medicines: safety and efficacy are assessed simultaneously and side effects are only allowed if the benefits exceed the risks.

For foods, the safety requirement is more absolute. *Foods must not provoke any health hazards*. The notion of food side effects would not be acceptable to consumers. There is one important exception to this: allergens in foods are allowed, and allergens can even be added to foods as additives. This means foods are basically *safe for people without allergies*. A further

¹⁴³⁰ The Government of Hong Kong Special Administrative Region. Food and Environmental Hygiene Department web page at: <http://www.fehd.gov.hk/safefood/foodlaw1.html>.

limit to absolute safety is that various harmful chemicals and contaminants are allowed in foods, as long as their amounts do not exceed the set maximum limits, see chapter 4. With regards to marketing claims, *medicinal claims are prohibited from foods*, but disease risk reduction claims are allowed if substantiated.

Businesses and consumers normally see functional foods as foods, not medicines. This can be derived from the term itself: the producers and marketers call their products *functional foods*. Consumers don't normally see functional foods as medicines, either. Functional foods are not taken to treat some acute condition; they are instead consumed to gain a future benefit. As opposed to foods, medicines are consumed to gain an immediate effect.

In EU law, the separation of foodstuffs and medicines is derived from their definitions. A functional food could be regarded as a medicinal product based on either its functions or its presentation. The definition of medicines says: *products are medicines if they:*

- A) *function as medicines and/or*
- B) *are presented as medicines.*

According to the definition of food, *those that are medicines are not foods*. A product cannot be both. An important clarification was recently added to the definition of medicines: *unclear cases are regarded as medicines*. Classification as medicine is legally possible for functional foods, because the previously mentioned definition of medicinal products does not exclude food-form products. A functional food could thus, according to EU law through pre-market authorisation or registration, receive the status of a medicinal product.

Basically, the marketer must himself know and decide whether the product belongs under food law or medicine law. The form of the product does not determine classification. The decision is based on product composition, the known effects of the product ingredients in human body, and the presented therapeutic use. When making the decision on which legal category to pursue, the benefits and costs of each option need to be weighed:

Firstly, the *pre-market procedures* are separate for foodstuffs and medicines. The possible novel food and health claim procedures for foods are demanding, but still not as burdensome as the herbal medicine authorisation procedure. The new registration procedure for traditional herbal medicines is available to some products.

Secondly, available claims differ between foodstuffs and medicines. For foodstuffs, health claims are allowed, but medicinal claims prohibited. *A food cannot have medicinal functions or medicinal claims*. Even if the product has significant health effects, we might be willing to settle for food status. This is because the consumer impact of a disease risk reduction claim might be almost as strong as that of a medicinal claim.

Thirdly, we must keep in mind that for medicinal products, there are limitations on available *marketing channels*¹⁴³¹. These marketing channels for herbals vary in different EU Member States. In Finland, around half of the authorised herbals authorised according to the old law can be sold in food stores, and the other half can only be sold in pharmacies. None of these herbals require prescription.¹⁴³² According to the new legislation, *herbal medicinal products*

¹⁴³¹ National Agency for Medicines web page at: http://www.laakelaitos.fi/laaketeollisuus/luokittelu/luokittelun_jalkeen/index.html

¹⁴³² National Agency for Medicines web page at: http://www.laakelaitos.fi/uploads/Laaketeollisuus/Rohdokset/Rohdosluettelo_2006_2_28.pdf.

can only be sold in pharmacies, but traditional herbal medicinal products can also be sold in food stores.

Even if we consciously decided to go with the medicine option, it might not be viable in practice. It might prove to be difficult or impossible to get a medicinal product license for something that looks, tastes, and feels like food. This is because the authorities seem to want to keep medicines and foods separate, regardless of their legal definitions. For example, the Finnish practice is “margarine cannot be medicine”.

We must also remember that the categorisation decision does not include authorisation. If a product is classified as a medicine, this decision does not entail that the product will be authorised as a medicine. It merely means that without appropriate pre-market procedures, the product is illegal. If the product is categorised as food, this decision does not amount to an approval that the product may legally be sold under food law. It merely means that the product must comply with food law requirements.

6.4.1.2 *Grounds for the Classification Decision*

At times we are unsure whether the functions of our product are medicinal. This typically means that our product contains healthy or medicinal ingredients but we still want to sell it as a food, for the aforesaid reasons. In this case, we either need to ask for a classification decision before we market the product, or just sell the product as food and wait for the authorities to possibly react.

Ultimately, national authorities resolve whether a product is a food or a medicine. This enables every EU Member State to divide functional foods into foodstuffs and medicines based on their own criteria. For example, according to Finnish law¹⁴³³, the National Agency of Medicines will, if needed, decide whether a substance or a preparation is to be regarded as a medicinal product. In unclear cases it is “recommended” that the producer apply for a classification decision.¹⁴³⁴

Categorisation in Finland is based on the pharmacopoeia drafted according to the Medicines Act¹⁴³⁵. The pharmacopoeia is a list of substances regarded as medicines, and it includes quality requirements for each medicinal substance. According to the Decision on the Pharmacopoeia, substances in Annex 1 of the Decision are medicines. Herbals in annex 2 and vitamins and minerals exceeding the daily dose in Annex 3 can be regarded as medicines¹⁴³⁶. Also other substances and herbals equivalent to substances and herbals in Annexes 1 and 2 and corresponding to the definition of medicines can be regarded as medicines.¹⁴³⁷ Basically, a product will be classified as a medicine, if it contains functional ingredients in *quantities that possess a pharmacological effect*. The definition of ‘pharmacological’ does not exist in law.

¹⁴³³ Section 6 of the Medicinal Products Act.

¹⁴³⁴ Food supplement guide, updated 2006. Page 19.

¹⁴³⁵ Section 83 of the Medicines Act states that the National Agency of Medicines must every third year, of more often if necessary, regulate on a pharmacopoeia (lääkeluettelo, list of medicines) that takes into account the definition of medicinal product etc.

¹⁴³⁶ A new pharmacopoeia (1179/2006) came into force in the beginning of 2007. Compared to the previous pharmacopoeia given three years earlier, no new herbs were added to Annex 2.

¹⁴³⁷ National Agency for medicines web page at: http://www.laakelaitos.fi/laaketeollisuus/luokittelu/luokittelun_perusteet/index.html.

If medicines, our functional berry products would be regarded as herbal medicines. An herbal medicinal product is a medicinal product exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations. *Herbal substances* are, among others, either dried or fresh plant parts. *Herbal preparations* are herbal substances subjected to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. Herbal preparations include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates. This means subjecting our berries to a technological procedure will not change their legal category. Dried or fresh berries would legally be herbal substances, and fractions and oils would legally be herbal preparations.

However, plant parts and plant extracts can of course also be used as foods. What resolves the issue of foodstuff vs. medicine is whether the product is either *presented* as a medicine or *functions* as a medicine. It is fairly easy to avoid our product being classified as a medicine by presentation. We simply must not mention that it will cure, treat or prevent a disease. For example, we cannot use claims like “for heart disease” or “to prevent diabetes”.

The medicinal function is more complicated. The new European definition of medicinal product addresses the issue of what kind of functions are to be considered medicinal functions. Substances which “may be used in or administered to human beings either with a view to *restoring, correcting or modifying physiological functions* by exerting a *pharmacological, immunological or metabolic action*” are medicinal products. It is also stated in the directive that any unclear borderline cases are to be treated as medicines, not foods. This new rule will also affect our situation: if we want to avoid our products being classified as medicines, we need to be certain that our products do not constitute unclear cases but are clearly foods.

What makes the categorisation decision more difficult is that the same plant raw material can be used in products categorised as foodstuffs and other products that will be categorised as medicines. Garlic is an example of a plant that can be used both as a food and as a drug. Garlic products are marketed in the European Union both as foodstuffs and as herbal medicinal products. All EU countries have garlic foodstuffs on their markets, and garlic medicinal products are available in some EU Member States.¹⁴³⁸ Likewise, the Finnish Food Agency has interpreted that a commonly known medicinal plant *Echinacea purpurea* can also be sold as food. In this case, the use of the medicinal plant must be based on something else than the medicinal effect of the substance or herb. It is clear that there may be two products on the market that contain the same substances or herbs but to which different rules apply. It is unclear what these, other than medicinal uses might be, in the case of *Echinacea*.

Because of different traditions in different EU countries, a product can be classified as a medicinal product in one EU Member State and as a foodstuff in another. Often the marketer would prefer the product being classified as food. For example, many products containing medicinal plants are in Germany classified as herbal medicinal products requiring a Product License, but are in Great Britain sold as foods without any pre-market approval. Some of the vitamin preparations that are classified as medicines in Finland are classified as foods in several Member States. Preparations that contain the hormone melatonin are classified as medicines in most European countries, but not all.¹⁴³⁹

¹⁴³⁸ Kroes 2006.

¹⁴³⁹ Enkovaara 2002, 22.

If we applied for a classification decision, and it resulted in our products being classified as medicines because of medicinal functions, we would have three alternatives:

- Withdraw from all plans of marketing.
- Apply for authorisation as herbal medicine.
- Change the product so that it no longer has medicinal functions, and then sell it as food.

6.4.1.3 Finnish Categorisation Cases

To predict the outcome of the categorisation decision, we might want to look at how similar cases have previously been treated. The Finnish Agency of Medicines has an online record of classification cases, classification decisions resulting in verdict 'non-medicine' since the beginning of 1995 and decisions resulting in verdict 'medicine' since the beginning of 2001¹⁴⁴⁰. The category of 'non-medicines' in practice includes foods and cosmetics.

The classification is in each case based on:

- the information given to the Agency by the applicant of the classification decision,
- the information given in product marketing, and
- scientific literature on the effects of product ingredients.¹⁴⁴¹

Again, the two important elements of the classification decision appear. These are product *functions* and the marketing *claims*.

In 2006 (published by 11 December 2006), there were 16 classifications as medicines, and 13 as non-medicines.

The *non-medicines* were:

- tiger balsam for sore shoulders, containing menthol, mint, eucalyptus etc.
- antiseptic mouth wash
- sport nutrition (recovery and fat-free muscle building)
- various food supplements containing vitamins (A,B,C,D,E), minerals, fish oils and omega three fatty acids
- Aloe Vera extract and vitamin C, food supplement
- salt for horses, for constipation
- clam etc. for dogs' joints
- Psyllium Ispaghula bark powder for horses, for problems related to eating sand.

Of these, only Aloe Vera and Psyllium Ispaghula were plant-based products.

If medicinal marketing claims, i.e. a therapeutic indication, had appeared on the Aloe Vera label, it would no doubt have been considered a medicine. Aloe Vera (in Finnish, medicinal Aloe) is on the Pharmacopoeia Annex 2 list on herbals that can be

¹⁴⁴⁰ They have also a third category, which covers health care appliances and devices.

¹⁴⁴¹ National Agency for Medicines web page at: <http://www.laakelaitos.fi/laaketeollisuus/luokittelu/luokittelupaatosia/index.html>.

regarded as medicines. Apparently, the medicinal function was in this case not strong enough for the product to be regarded as a medicine.

Psyllium Ispaghula is used for stomach troubles because of its fibre content¹⁴⁴². The plant is not listed in the pharmacopoeia, and has no pharmacological effect and therefore it is regarded as food, not medicine.

The *medicines* in 2006 were:

- Melon extract etc. for vitiligo¹⁴⁴³
- Glucosaminesulfate for joints
- Benzoylperoxide for acne
- Antibacterial mouth wash
- *Spirulina platensis* (algae) for malnutrition and lack of nutrients
- *Citrus aurantium*, green tee extract, guarana extract etc. for weight management
- ‘Amino acid enzymes’, hawthorn berry extract, vitamins etc. for digestion (two products)
- Colostrum¹⁴⁴⁴, *Echinacea purpurea*, eucalyptus, menthol and vitamins for sore throat
- Cranberry extract for urinary tract infections¹⁴⁴⁵
- Saw palmetto (*Sabal serrulata*)¹⁴⁴⁶ extract, nettle¹⁴⁴⁷ extract, lycopene for prostate problems and impotence¹⁴⁴⁸
- Boswellia¹⁴⁴⁹ extract etc. for arthrosis¹⁴⁵⁰
- *Vaccinium myrtillus* (blueberry) and *Tagetes erecta*¹⁴⁵¹ etc. for night vision and eye diseases¹⁴⁵²
- Soy, vitamins etc. for eye health¹⁴⁵³
- *Symphytum officinalis* (blackwort)¹⁴⁵⁴ extract etc. for joints, muscles, bruises, cuts etc.
- *Annona muricata*¹⁴⁵⁵ powder for health enhancement and immunity.

¹⁴⁴² “Psyllium is a soluble fibre used primarily as a gentle bulk-forming laxative. It comes from a shrub-like herb called plantain that grows worldwide.” Atlanta Journal-Constitution web page at: http://www.ajc.com/health/altmed/shared/health/alt_medicine/ConsSupplements/Psylliumcs.html.

¹⁴⁴³ Also known as leukoderma, in Finnish: valkopälvi.

¹⁴⁴⁴ In Finnish: ternimaito. The milk that a cow produces after giving birth.

¹⁴⁴⁵ The applicant had classified the product as a food supplement, but medicinal claims had been presented in advertising.

¹⁴⁴⁶ In Finnish: sahapalmu.

¹⁴⁴⁷ In Finnish: nokkonen.

¹⁴⁴⁸ The applicant had classified the product as a food supplement, but medicinal claims relating to prostate problems and impotence had been presented in advertising.

¹⁴⁴⁹ Boswellia is a genus of trees that have pharmacological uses particularly as anti-inflammatories. Wikipedia.

¹⁴⁵⁰ The applicant had classified the product as a food supplement, but medicinal claims relating to arthrosis (In Finnish: nivelrikko) had been presented in advertising.

¹⁴⁵¹ In Finnish: isosamettikukka.

¹⁴⁵² The applicant had classified the product as a food supplement, but medicinal claims had been presented in advertising.

¹⁴⁵³ The applicant had classified the product as a food supplement, but medicinal claims had been presented in advertising.

¹⁴⁵⁴ In Finnish: rohtoraunioyrtti.

¹⁴⁵⁵ Other names: Graviola, soursop, Brazilian paw paw, guanábana. Raintree Nutrition company web page at: <http://www.rain-tree.com/graviola.htm>.

In this list, there are several plant-based products. In 2006 the Agency had not specified whether the classification was based on medicinal claims or product function. It is clear that almost all of the above-listed products would have been classified as medicines just because of the *claim* used. If a product is marketed for prevention or treatment of a disease, it is always considered a medicinal product. One cannot claim, for example, “for vitiligo” or “for arthrosis” if one wants to sell the product as food.

Some of the above could also have been classified as medicinal products by *function*, even without medicinal marketing claims. For example *Echinacea*, *Symphytum officinalis* and *Sabal serrulata* are well-known medicinal plants that are listed in the pharmacopoeias. Products containing these plants are classified as medicines, if they are present in quantities that have a pharmacological effect on the body.

Cranberry and blueberry of the berries in the above list are not listed in the pharmacopoeia, even though they do have scientifically proven health functions. Hawthorn, on the other hand, is listed in the pharmacopoeia. We will return to the three chosen berries (hawthorn, emblic leafflower, and barberry wolfberry) in the next chapter.

The *non-medicines of the year 2005*, consist of, for example:

- pastille containing 17 % Aloe Vera juice
- artichoke ginseng tea, 99 % artichoke, 1 % ginseng
- herbal tea containing: 90 % Mulberry, 10 % *Chrysanthemum* flower
- refreshing drink containing *Angelica archangelica*¹⁴⁵⁶ leaf extract
- muscle relaxing massage cream containing *Angelica archangelica* etc.
- food supplement containing: *Kaempferia pafiflora* 75 mg, *Butea superba* 50 mg, *Zingiber officinale* 50 mg, *Anamitra Cocculus W & A*-leaf 25 mg, *Nelumbo nucifera* Gaertner-leaf 25 mg, *Piper nigrum*, linnseed 25 mg
- herbal tea containing: *Polygonum multiflorum* 15 %, *Tinaspora sinensis* mer 50 %, *Piper lolot C* 10 %, *Glychyrrhiza uralensis* 5 %, *Cortex acantho panasis* 10 %, *Rhizoma imperatae* 10 %.

The refreshing drink product contained *Angelica archangelica* 1.09mg/l. The massage cream contained *Angelica archangelica* 0.6 %. *Angelica archangelica* is a commonly known medicinal plant, and the decisions to categorise these two products as foods were based on the low quantities of the medicinal plant.

The *non-medicines from 1995 to the end of June 2004* consist of:

- Aloe Vera use (1996)
- Ecoway Noni (2001)
- Ginseng Tea (Special) (2003)
- Guarana brasil (1996)
- Maui Noni (1 tablet every 3rd day) (2004)
- Green Echinacea tea (2003)

This information from before 2005 is not very useful as the compositions of the products are not given and it is not explained why the product was classified as a non-medicine.

¹⁴⁵⁶ In Finnish: väinönputki.

Medicines from 2001 to 2005¹⁴⁵⁷ consist of, for example:

- Ginseng tablet, containing ginsenosides 8.3 mg/tablet
- Ginseng extract, corresponding to 340mg ginseng root/tablet
- Ginseng root 100mg
- Ginseng extract 100mg, ginsenosides 24mg/tablet
- Ginseng extract 100mg, 80mg ginsenosides
- Ginseng radix 70%
- Ginseng (ginsenosides 8mg)
- *Echinacea radix* 400mg
- *Echinacea* extract 33.6% (168.7mg /tablet)
- *Silybum marianum* (milk thistle, holy thistle)¹⁴⁵⁸ extract
- *Cordyceps sinensis* (Cordyceps mushroom, caterpillar fungus)¹⁴⁵⁹ 75%
- *Cordyceps sinensis* 1000µg. Chrome 200µg. sport nutrition
- *Cordyceps sinensis* (part of powder mix) 2.61g/11.8g, *Ginkgo biloba*¹⁴⁶⁰ (part of powder mix) 1.15g/11.8g
- *Ginkgo biloba* tea 15% (0.3g/tea bag)
- *Valeriana officinalis* (valerian)¹⁴⁶¹ 44g fresh root/ 100g powder
- *Valeriana officinalis* 600mg
- *Sennae folium* (senna leaf)¹⁴⁶² tea 30%
- *Frangulae cortex*¹⁴⁶³ tea 30%
- *Eleutherococcus senticosus* (*Acanthopanax senticosus*, green ginseng)¹⁴⁶⁴ 15% (0.3g/tea bag)
- Nappy rash cream, *Hypericum perforatum* (St. John's Wort)¹⁴⁶⁵ 14.5%, *Arnica Montana* (mountain arnica)¹⁴⁶⁶ 1.9%
- Liquorice containing *Hypericum perforatum* 0.1%, *Valeriana officinalis* 0.1%, *Cimicifuga rasemosa* (black cohosh, black snakeroot)¹⁴⁶⁷ 0.1%

The list of products classified as medicines in 2001 to 2005 is useful, as the Agency has provided grounds for each classification decision. All of the above were categorised as medicines based on their function. If a product is categorised as a medicine by function, it means the product has physiological or pharmacological effects on the body. In these cases this was due to the presence

¹⁴⁵⁷ National Agency for Medicines web page at: <http://www.laakelaitos.fi/uploads/Laaketeollisuus/luokittelu/laakkeet2001-2005.pdf>.

¹⁴⁵⁸ In Finnish: maarianohdake. This plant is used in liver diseases because it enhances liver tissue renewal. Yrttitarha project web page at: <http://www.yrttitarha.com/kanta/maarianohdake/>.

¹⁴⁵⁹ In Finnish: kiinanloisikka. This is a mushroom used in traditional Chinese medicine for general well-being as it helps the liver, kidneys, etc. Sahelian, Ray: web page at: <http://www.raysahelian.com/cordyceps.html>.

¹⁴⁶⁰ In Finnish: neidonhiuspuu.

¹⁴⁶¹ In Finnish: rohtovirmajuuri.

¹⁴⁶² In Finnish: sennan lehti.

¹⁴⁶³ In Finnish: paatsaman kuori.

¹⁴⁶⁴ In Finnish: venäjänjuuri.

¹⁴⁶⁵ In Finnish: mäkikuisma.

¹⁴⁶⁶ In Finnish: etelänarnikki.

¹⁴⁶⁷ In Finnish: tähkäkimikki.

of *high quantities of the medicinal plant*. The Agency must base their decision on scientific facts, particularly on the effective doses of each plant.

In 2001 – 2005 there were numerous products categorised as medicines based on the marketing claim. These were products marketed for menopause and female hormonal changes, impotence and male performance, psoriasis, urinary tract infections and prevention of kidney stones, impotence, and depression or anxiety, for example. In these cases, the Agency did not even have to look at the function of the product, as the claims were medicinal. The Agency probably considered these as relatively simple cases.

When investigating the above lists of categorisation decisions, we must keep in mind that legislation changed in November 2005. That is when the implementation legislation of directive 2004/24/EC came into force in Finland. This directive included a change in the definition of a medicinal product, and created the new category of traditional herbal medicinal products. Based on the Finnish legislation¹⁴⁶⁸ implementing directives 2004/24 and 2004/27, *the new legislation in fact shifted the borderline between medicines and foods, so that former foods may now be considered medicinal products*. This can be inferred from the transitional regulations:

- If a product has received product authorisation according to old legislation, and the product corresponds to the definition of traditional herbal medicinal product according to new legislation, the National Agency of Medicines will change the product license into product registration, when renewed.
- If a product has received product authorisation according to old legislation, and does not correspond to the definition of traditional herbal medicinal product according to new legislation, product authorisation according to new legislation must be applied for, when renewed.
- *If a product has been classified as a foodstuff according to old legislation, and the product corresponds to the definition of traditional herbal medicinal product according to new legislation, registration as a traditional herbal medicinal product must be applied for by the end of 2007.*

Here we see that ‘traditional herbal medicinal product’ is by Finnish legislators seen as a legal category consisting of both former medicines and of former foods. This means that some of the products previously categorised as foodstuffs could now be regarded as medicines.

The change in the definition of medicinal product in the Finnish law of November 2005 corresponds to the change of the directive 2004/24/EC. In the new definition¹⁴⁶⁹, the medicinal action is more precisely defined as “pharmacological, immunological and metabolic action”. This clarification as such does not shift the borderline between foodstuffs and medicines, and the Finnish lawmakers agree on this.

How is it then possible that some of the products previously classified as foods might according to the new legislation be classified as traditional herbal medicinal products? This outcome must be based on the notion that according to new legislation, *unclear cases are to be*

¹⁴⁶⁸ Laki lääkelain muuttamisesta. 4.11.2005/853.

¹⁴⁶⁹ Finnish Medicines Act section 3.

categorised as medicines. The Finnish law now includes the same rule¹⁴⁷⁰ as the directive¹⁴⁷¹: unclear cases are to be treated as medicines, in cases where a product corresponds to the definition of a medicinal product and also the definition of some other product (for example food but also medical devices and cosmetics).

Before the selection rule existed, unclear cases were apparently sometimes treated as foods, sometimes medicines. We might presume that all EU Member States have understood the new rule in a similar manner, and that the borderline has in fact somewhat shifted towards medicines. This means we cannot rely on any ‘non-medicine’ categorisation decisions by any EU Member States from before 2005 for comparison to our products.

6.4.1.4 Probable Categorisation of the Three Berries

Hawthorn is used as herbal medicine in Europe. In Western herbalism, hawthorn fruit, leaf, and flower have all had a long history of use for treating cardiac weakness, and this has become a focus of modern research.¹⁴⁷² For example, in the Finnish Pharmacopoeia, hawthorn (*Crataegus*) is listed in Annex 2: herbals that could be considered as medicines. This does not mean that products made of hawthorn are automatically regarded as medicinal products. Instead, it means that products containing hawthorn in quantities that have pharmacological effects on the body, are considered as herbal medicines.

At the moment (end of 2006), there are two authorised herbals based on hawthorn on the Finnish market: both in the form of tincture and both used for mild heart conditions. It has to be noted, that these products have been authorised under the old law on herbal medicines. Both can be sold in the Finnish food stores¹⁴⁷³. In the future, these products will have to be authorised as herbal medicinal products or registered as traditional herbal medicinal products according to the new legislation.

Emblic leafflower and *barbary wolfberry* are not listed in the European Pharmacopoeias. The classification decisions of products would have to be based on evaluation of the pharmacological properties of the product. Products would not automatically be classified as herbal medicinal products just because emblic leafflower and barbary wolfberry are known medicinal plants. Again, the dosage is important. If medicinal plants are present in quantities possessing ‘pharmacological effects’, products will likely be considered as medicines.

Besides through medicinal function, presenting medicinal claims is the other route for our products to achieve medicinal status. As stated above, medicinal claims are of the type “for prevention of diabetes” and “for heart conditions”. Mention of the metabolic syndrome would also constitute a medicinal claim.

¹⁴⁷⁰ Finnish Medicines Act section 3(3).

¹⁴⁷¹ Medicinal products directive, Article 2(2).

¹⁴⁷² *Crataegus laevigata*, *Crataegus monogyna* and *Crataegus oxycantha* are the species used in Europe and they are different from the Chinese hawthorn (*Crataegus pinnatifida*). Dharmananda.

¹⁴⁷³ National Agency for Medicines web page at: http://www.laakelaitos.fi/uploads/Laaketeollisuus/Rohdokset/Rohdosluettelo_2006_2_28.pdf.

6.4.2 China

In China, foodstuffs and medicines are traditionally seen as substances from the same source. Many herbs can be sold either as health foods or traditional Chinese Medicines. This is the case for our berries: all three berries are on the market both as food and as herbal medicines. If we want to develop functional food products to the Chinese market, there is legally room for different types of products made of the three berries. The two basic legal alternatives are health foods and traditional Chinese medicine.

Chinese legislation separates foodstuffs and medicines based on product functions. *Health foods* form the relatively clearly defined borderline category between regular foods and medicines.

‘Health foods’ category is suitable for products that:

- possess the general nature of food,
- can regulate bodily functions of certain consumer groups, but
- are not intended for therapeutic purposes.

The Health Food Regulation establishes 27 possible health-related functions for health foods, including regulation of blood pressure, regulation of blood lipids, and regulation of blood sugars. These are the health claims also available to marketers. The health foods category is suitable for us as we are functional food developers fighting the metabolic syndrome. If we were interested, for example, in cancer risk reduction, the health food category would not be available. The application for health food registration is sent to the SFDA, and several different research reports on safety, efficacy and quality of the product are required.

Traditional medicines, on the other hand, are plant-based medicines, sold for a therapeutic purpose, to prevent or treat a disease. For these, an application to the SFDA is necessary. Traditional medicines are evaluated according to the Medicine Administration Law.

6.5 General Safety Requirements

General safety requirements for consumer products, and foodstuffs and medicines in particular, were discussed above in chapter 4.

6.5.1 EU

According to general rules on product safety, it is illegal to sell unsafe products to consumers including products that are hazardous and products on which the consumer is not given enough information to enable safe use.

European *food safety* requirements are strict. Foods must not be dangerous to a person’s health. Besides short-term health effects, also long-term health effects, cumulative health effects and effects on subsequent generations are taken into account when determining safety criteria. The precautionary principle guides the risk analysis.

General requirements applicable to all foods include *biological safety and chemical safety*. Biological safety is guaranteed by hygiene rules. In Europe, the separate hygiene rules for

different types of products, for example meat, eggs and milk, were recently codified into one single Regulation. Chemical safety of foods is guaranteed by regulating residues, contaminants, additives, and food contact materials. GMO foods have their own authorisation procedure.

Functional foods are sometimes *fortified* by vitamins and minerals. Here one must follow the EU Regulation on food fortification. With regard to substances other than vitamins and minerals, national rules on fortification apply. The Regulation on food supplements gives the rules on allowed vitamins and minerals in these products. In the future, the Regulation on food supplements will probably also cover other substances than vitamins and minerals, for example herbals. Until that time, national rules on food supplements apply. If one wants to sell the product as a *dietetic food*, particular compositional and quality criteria are given in specific directives.

Medicine safety is evaluated concurrently with efficacy. *Potential risks must be outweighed by therapeutic efficacy*. Safety of medicines is guaranteed by procedural requirements relating to tests and trials that have to be performed and documented before authorisation is granted. There are simplified procedures for certain medicines that are considered safe and effective without a need to provide a complete dossier of documents.

With *new chemical and herbal medicines*, the application must include a complete dossier of documents. This dossier contains information on the results of physico-chemical, biological or microbiological, pharmacological and toxicological tests.

Applications can also be based on:

- essential similarity to existing medicines, or
- scientific literature to prove a *well-established medicinal use* with recognised efficacy and an acceptable level of safety.

Applications on *traditional herbal medicines* can also be based on a history of safe use. The required ‘history’ is defined as 30 years of use, of which 15 years within the European Community area.

Homeopathic medicines can be authorised via the primary procedure just like other medicines. There is also a simplified procedure for homeopathic medicines that bear no therapeutic indication and are sufficiently diluted to make them harmless. With herbal medicines, lowering the dose will make the product a food; in homeopathy it will make the product eligible for simple registration as a medicinal product. Because of different cultural traditions, the simplified procedure does not exist in all the EU Member States.

6.5.2 China

The Chinese food safety legislation consists of similar pieces of law as its European counterpart. Both biological and chemical safety is regulated. Food hygiene is regulated nationally through the Food Safety Law. In addition, there are separate decrees giving specific hygiene rules on food irradiation, meat and meat products, milk and milk products, eggs and egg products, aquatic products, condiments, sugar, alcohol, grain, edible vegetable oil, tea, edible mushrooms, street food, student food etc.¹⁴⁷⁴. Local authorities issue the food hygiene

¹⁴⁷⁴ Kan – Zhang 2002.

licenses to manufacturers and sellers¹⁴⁷⁵. Also day-to-day control of food hygiene is under the competence of local authorities. This is why hygiene rules in practice vary in different parts of China.

Chemical safety is the goal of regulations on food additives, environmental contaminants, pesticide residues, hormones and antibiotics residues, food contact materials etc¹⁴⁷⁶. GMO legislation is also in place. The Chinese Ministry of Agriculture has established the pollution-free-program and the green program to produce food without harmful chemicals. However, these programs are not yet commonly followed.

According to general rules on medicine safety, the sale of fake medicines and medicines of inferior quality is prohibited. With modern medicines, safety is based on pre-clinical and clinical trials. With traditional medicines, safety evaluation is often based on long tradition of use. However, the safety approach to traditional medicines is similar to that of modern medicines: all medicines are recognised to have side effects, a risk-benefit ratio is applied, and appropriate dosage is an integral part of treatment.

6.6 Particular Safety Criteria of Novel Foods

Functional foods often have new ingredients the use of which might involve new types of health hazards. The safety of a functional food will in these cases have to be evaluated pre-market according to *novel food legislation*. We need to consider whether our berry products (if considered foods, not medicines);

- would be considered novel foods, and if so,
- what would be the procedure to determine their safety, and
- whether they would be authorised as legal novel foods.

These questions are evaluated based on novel food regulations and literature¹⁴⁷⁷, and in comparison to existing novel food products.

6.6.1 Current EU Novel Food Regulation

6.6.1.1 *Would berries be considered novel?*

In the EU, a food that has not been marketed to a *significant degree* before May 1997 is considered novel. Novel foods must go through the pre-market authorisation procedure, where an application is first sent to a Member State, and where all EU Member States thereafter have their say on whether the food should be authorised. A simplified procedure (notification) is available to those novel foods that are *substantially equivalent* to existing foods.

¹⁴⁷⁵ Food safety authorities in provinces, autonomous areas, and municipalities directly under the central government.

¹⁴⁷⁶ Kan – Zhang 2002.

¹⁴⁷⁷ Discussed above in chapter 4.2.

It is evident that hawthorn berries are not novel foods as the plant has been commonly used as food in Europe for decades. It is now used as a food supplement¹⁴⁷⁸ and as regular food¹⁴⁷⁹.

We have a recent opinion on the novelty of barbary wolfberry by the UK's Food Standard Agency (FSA). According to the FSA, consumption of *Lycium barbarum* (Chinese wolfberry, goji berry) has been significant for many years, and more importantly, before May 1997. Therefore the berry does not need to be authorised as a novel food. The FSA started seeking evidence of goji consumption in February 2007. According to initial reports, no significant history of consumption before 1997 was evident. This would have resulted in the requirement of the fruit to be authorised as a novel food. Products containing wolfberries are at the moment being sold on the UK market.¹⁴⁸⁰

With emblic leafflower fruit, the situation is more difficult. We can first take a look at other plant-based foods that have been considered novel. The three plant-based novel foods that have gone through the authorisation procedure are: *Stevia rebaudiana* Bertoni, Nangai nuts, and Noni fruit¹⁴⁸¹. Among the notified novel foods, there are for example prune kernel oil and argan oil. All of these were not novel foods as such, as they had significant history of food use outside Europe, but apparently no history of food use in Europe was found.

Basically, the marketer must know whether his product is novel. It is illegal to market novel foods without authorisation. If the marketer is not sure of novelty, they can search the European market themselves, and ask for guidance from the national food safety authority of their EU Member State. If a novel food application is made, the food safety authorities will perform a literature search and a field study to determine whether the food is in fact novel.

We have superficially searched through literature and the Internet and not found European food use of emblic leafflower. We thus predict that emblic leafflower fruit as a functional food ingredient would indeed be considered a novel food in Europe.

6.6.1.2 *Would the berries be eligible for the simplified procedure?*

According to the current novel food regulation, certain novel foods or novel food ingredients may follow a simplified procedure, which only requires notification from the company. This is when the foods are considered (by a national food assessment body) as “*substantially equivalent*” to existing foods or food ingredients. This assessment of substantial equivalence is based on the composition, nutritional value, metabolism, intended use, and the level of undesirable substances contained in the food. If considered novel, we must consider whether the three berries would be eligible for the simplified procedure, or whether they would need authorisation according to the principal procedure.

So far (September 2006), around 70 notifications on novel foods have been made. This means that these 70 products were regarded as novel, but essentially similar to existing foods.

¹⁴⁷⁸ For example the Finnish herbal company Frantsila and the Swedish herbal company Örtagubben use hawthorn in food supplements: <http://www.frantsila.com/m-tuotteet-yrttiuutteet.htm>, <http://ortagubben.jetshop.se/default.aspx>.

¹⁴⁷⁹ This can be inferred from various marmalade recipes on European homepages, for example <http://kerkka.vuodatus.net/blog/archive?m=09&y=2006>, <http://www.recepthjalpen.se/hagtorn.html>.

¹⁴⁸⁰ Nutraingredient.com Europe News Headlines 18/06/2007.

¹⁴⁸¹ The details of the authorisation processes for these three foods will be discussed below.

Of these, around 30 concerned noni fruit. In addition, there were notifications on prune kernel oil and argan oil. Prune kernel oil, huile d'amandon de pruneau, was notified in July 2000. Argan oil (*Argania spinosa* L.) was notified first in July 2002 and subsequently in 2005 and 2006. Other novel foods notified were a vitamin, a fungus, a couple algae, and around 30 products with added phytosterols or phytostanols often by companies extending their cholesterol-lowering product lines.¹⁴⁸²

Noni juice was already mentioned above. After it received authorisation in 2002, several people and companies have notified it. A German first notified it in November 2003. Subsequently, several German, French, Danish, and Dutch actors have notified it. All of the notifications were based on an assessment by national food agency that the product in question is similar to the original noni juice authorised as novel food.¹⁴⁸³

In the previous chapter, we concluded that hawthorn and barbary wolfberry would not be considered novel in Europe. To be eligible for the simplified procedure, emblic leafflower fruit would need to be considered substantially equivalent to some other berry. So far, notification process has been used only to bring to market *the same fruit (noni)* that has already been authorised through the primary procedure. We thus predict that emblic leafflower fruit would not be considered equivalent to any other berry.

6.6.1.3 *Would the berries be authorised?*

If considered novel and not eligible for the simplified procedure, we must predict whether our functional food products would be authorised in the primary procedure for novel food safety evaluation. According to the law, a novel food can be authorised if it is safe for consumers to use. Novel food assessment integrates nutritional and toxicological aspects: nutritional properties of the food and the predicted dietary exposure affect the toxicological testing programme. Besides science, novel food evaluation is in practice also affected by different cultures and different political interests of EU Member States. According to exotic food producers, the safety requirements for novel foods are so strict that for example wheat, potatoes and green leafy vegetables would not be accepted if now introduced in Europe.

Based on the current legislation, only one novel food product that even resembles berry-based products has been authorised: the noni juice. Two plant-based novel foods have been rejected. These are *Stevia rebaudiana* Bertoni¹⁴⁸⁴ and Nangai nuts (*Canaria indicum* L.)¹⁴⁸⁵ It is noteworthy, that of the three novel foods rejected since 1997, two were plant products. All the products containing stanols or sterols have been authorised. Currently novel food safety requirements concerning so-called exotic plants are strictly interpreted in Europe, and producers of these plants are demanding some relief to these requirements.

¹⁴⁸² European Commission web page at: http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf.

¹⁴⁸³ European Commission web page at: http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf.

¹⁴⁸⁴ Commission Decision 2000/196/EC.

¹⁴⁸⁵ Commission Decision 2001/17/EC.

Stevia case

The Commission's Scientific Committee on Food gave its opinion¹⁴⁸⁶ on *Stevia rebaudiana* Bertoni in June 1999. Information on the chemical composition of the plant leaves was available to the Committee. The leaves contain a complex mixture of natural sweet chemicals, the main sweet principle being stevioside.¹⁴⁸⁷ There was data showing stevioside is not toxic. The Committee also knew the plant in question is *a traditional American natural sweetener used for centuries*. It has been added to herbal teas and other beverages.¹⁴⁸⁸ They also knew that the plant was cultivated in several American and Asian countries, as well as in Europe¹⁴⁸⁹. Botanically, the plant was well identified¹⁴⁹⁰. There were no particular technological processes involved, only drying¹⁴⁹¹ and thus it is safe to say that using the plant in foods was not a discovery of any kind.

In Paraguay, the plant had since the 50s been *administered to diabetics* to reduce blood sugar levels. The applicant had also provided results of one *animal test* proving this kind of benefits to diabetics. According to the applicant, a significant decrease in liver glycogen after 2 weeks and a significant decrease in blood glucose levels after 4 weeks were showing in the rat test. The Committee did not consider this animal test convincing, as they did not have the details of the study.¹⁴⁹² The dry powder was intended to replace some of the sucrose in drinks, jams and sweets to reduce the caloric intake. Besides diabetics, the product was also considered good for obese individuals.

The Committee would have wanted more information, though. They would have liked the product to be carefully analysed, and the composition standardised, preferably with regard to stevioside. The producer should have known where the plants are cultivated, which variety of the species will be used, and what the composition of commercial products is. Also *toxicological tests* on the final products should have been helpful, even though nothing inherently toxic is present in the plant. Also *microbiological issues* should have been addressed in the application.¹⁴⁹³ The *appropriate intake* was also unclear to the Committee. There were also no studies to show the *physiological and pharmacological effects* of substituting sugar with *Stevia rebaudiana* in diabetic or obese individuals.¹⁴⁹⁴ There were also no studies on how the use of the plant might affect absorption of other food.¹⁴⁹⁵ The list continuing, no investigations on the *allergenic potential* of the leaves and the powdered leaves were submitted.¹⁴⁹⁶

¹⁴⁸⁶ Opinion on *Stevia Rebaudiana* Bertoni plants and dried leaves. Expressed on 17 June 1999 Scientific Committee on Food. SCF/CS/NF/STEV/3 Final 17/6/1999

¹⁴⁸⁷ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

¹⁴⁸⁸ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 2.

¹⁴⁸⁹ *Stevia Rebaudiana* Bertoni was cultivated in Paraguay, Mexico, Central America, Japan, China, Malaysia, and South Korea. Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 2. In Europe it was reported to be cultivated in Spain, Belgium and the UK. In Europe, the plant was cultivated in greenhouse conditions, as it does not survive winter climate. Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

¹⁴⁹⁰ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

¹⁴⁹¹ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

¹⁴⁹² Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 4.

¹⁴⁹³ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 3.

¹⁴⁹⁴ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 4.

¹⁴⁹⁵ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 4.

¹⁴⁹⁶ Opinion on *Stevia rebaudiana* Bertoni as a novel food, page 5.

The list of missing information includes issues that should not be relevant in novel food assessment. Microbiological issues are under general European food law, and hygiene rules apply similarly to non-novel and novel products. Novel food assessment is not about whether hygiene rules are obeyed. Similarly, it does not prevent a food from being authorised if it has allergenic potential. Many common foods have allergenic potential, and labelling allergens is another issue from novel food assessment.

The conclusion of the Scientific Committee was that there was *not enough information* available to evaluate the safety of the plant. There was no data to support safe use of it as food ingredients or as sucrose substitute for diabetics and obese individuals.¹⁴⁹⁷ On the same date (17 June 1999), the Committee also gave its negative opinion on the use of it as a food additive¹⁴⁹⁸. The additive process is legally separate from the novel food process, but the decisions were intertwined. The outcome of the process is that Stevia plants and stevioside as a sweetener are banned in Europe. Nevertheless, they have appeared on the market¹⁴⁹⁹.

If we look at the opinion on stevioside as a food additive, we can better understand why the application on Stevia as novel food was rejected. There have been several studies on stevioside and its metabolite steviol. Particularly steviol seems to be problematic, as it has been shown to decrease fertility in male rats and to include developmental toxicity. It has been reported to cause cancer when fed at very high doses to rodents.¹⁵⁰⁰

Nangai nuts case

Nangai nuts¹⁵⁰¹ (*Canarium indicum* Linné, kenari nuts¹⁵⁰², ngali nuts, galip nuts, java almonds) are the other example of a plant product that has been rejected as novel food in EU.

The request to market nangai nuts was made on behalf of a Vanuatu company called Pacific Nuts Ltd. The request was submitted to the French authorities in December 1998. The initial assessment report by the French competent authorities concluded that the product is safe for human consumption and could therefore be authorised. The French decision was subject to certain recommendations regarding microbiological controls, regular monitoring of aflatoxin levels and labelling requirements similar to those for nuts in general because of potential allergenic risks.¹⁵⁰³ This meant the French were willing to treat nangai nuts as quite harmless products, and considered normal precautions adequate.

However, objections were raised by four other Member States. Therefore, the Scientific Committee for Food had to assess the product. They gave their opinion in March 2000, stating that *data necessary for the assessment of the safety of the product is lacking*. They said the product should not be authorised.¹⁵⁰⁴

It was at this stage of the procedure when the applicant claimed that nangai nuts are in fact not a novel food at all. The applicant claimed that these nuts were consumed in the Netherlands

¹⁴⁹⁷ Opinion on Stevia rebaudiana Bertoni as a novel food, page 5.

¹⁴⁹⁸ Opinion on stevioside as a sweetener, adopted on 17/6/1999. SCF/CS/ADD/EDUL/167 final.

¹⁴⁹⁹ <http://www.food.gov.uk/news/pressreleases/2000/jun/stevioside>.

¹⁵⁰⁰ Opinion on stevioside as a sweetener.

¹⁵⁰¹ This is what the nuts are called in Vanuatu.

¹⁵⁰² This is what the nuts are called in Indonesia.

¹⁵⁰³ Opinion on nangai nuts as novel food, page 2.

¹⁵⁰⁴ 2001/17/EC: Commission Decision of 19 December 2000 on refusing the placing on the market of “Nangai nuts” (notified under document number C(2000) 3888).

to a significant degree. This claim was examined by the Dutch authorities who could not find such nuts. Nangai nuts were considered novel foods. The decision prohibiting nangai nuts was issued in December 2000.¹⁵⁰⁵ This means it took two years to assess the safety of these nuts.

The opinion of the Scientific Committee¹⁵⁰⁶ was based on similar facts as it was in the Stevia Rebaudiana Bertoni case described above. Again, not enough tests had been completed on the plant.

The Committee knew that the almonds were widely used in the Pacific region. The estimated consumption of ngali nuts in Western Melanesia was about 60 tonnes of almonds or about 70 g/day/person¹⁵⁰⁷. No particular technology was involved, besides drying, floating, soaking and drying again. The Committee also knew that Ngali nuts are listed in the Australian tables of composition of Pacific Island Foods and that the nutrient content of the kernels had been analysed. From nutritional point of view, the Committee stated that nangai nuts are practically the same as nuts eaten in Europe.¹⁵⁰⁸

The applicant had performed various tests on the nuts. They had for example tested the nuts for heavy metals and mycotoxins. *The Committee would have wanted more information*, though. They said not all the relevant mycotoxins were present in the studies performed. The applicant had tested the product for four different aflatoxins, but not for other mycotoxins. According to the Committee, the information on the analytical methods employed when determining the nutritional composition of the nuts was not adequate. Information on the storage conditions of the samples was insufficient. The Committee said that the product does not comply with the EU hygiene standards. They were also missing toxicological assessment of the nuts and wanted information on potential genotoxicity of the nuts.¹⁵⁰⁹ Also the allergy issue was mentioned: the possible allergenicity of the nuts had not been investigated.

It is interesting how the Committee ends its Opinion: “no conclusions can be drawn on the safety ... , *if the assessment procedures ... have to be followed strictly*.”¹⁵¹⁰ Even the Scientific Committee of Food, the drafter of the legal texts, did not seem to know whether the procedures, laid down in the Regulation and in the Recommendation, were meant to be strictly followed. They left the door open for the Commission to make the ultimate decision. The Commission then decided that the nuts should be prohibited based on insufficient information. This suggests that the Commission answered ‘yes’ to the question of whether the procedures have to be strictly followed.

Noni case

The application to put Noni (*Morinda citrifolia* L., Indian mulberry) juice on the market was made by a U.S. company, Morinda Inc., in April 2000.¹⁵¹¹ The request to market the

¹⁵⁰⁵ Commission Decision 2001/17/EC.

¹⁵⁰⁶ Scientific Committee on Food. Opinion on the safety assessment of the nuts of the Ngali tree (expressed on 8 March 2000). SCF/CS/NF/DOS/5 ADD 1 REV 3 final 14/03/00.

¹⁵⁰⁷ Opinion on nangai nuts as novel food, page 2.

¹⁵⁰⁸ Opinion on nangai nuts as novel food, page 3.

¹⁵⁰⁹ Opinion on nangai nuts as novel food, page 3.

¹⁵¹⁰ Opinion on nangai nuts as novel food, page 4.

¹⁵¹¹ The product in question was not exactly Noni fruit itself, but “Tahitian Noni” juice, a fruit juice mixture of 89 % Noni fruit (*Morinda citrifolia* L.) and 11 % common grape and blueberry juice concentrates and natural flavours.

product was addressed to the Belgian authorities. In the initial assessment report, the Belgians rejected the application and concluded that additional assessment was required. The Scientific Committee gave its Opinion in December 2002¹⁵¹², and Commission's decision authorising the product followed in June 2003.¹⁵¹³ This time the procedure took over three years.

The Belgian authority had rejected the application based on inadequate toxicological tests: the doses used in the original tests were too low. They would also have liked to know the place of noni in the diet.¹⁵¹⁴ Member States objected noni juice for various reasons: besides toxicological and allergy studies, they focused on health claims and the medicinal nature of the product.¹⁵¹⁵

Here we can see that the purpose of the novel food regulation was not clear: is it just for determining safety as such? Or should it include assessment of the functional food properties of the food? The fact is that often the novel ingredient in a food is added because of its health effects. This is also the case with our berries: we want to use them in novel functional foods because they have health effects. The question of *whether marketing claims are a separate issue from safety assessment* is now getting clearer: the new regulation on nutritional and health claims creates a framework for all food claims. The claims are thus not evaluated in the novel food procedure.

In this case, the applicant had closely followed the Recommendation on how to structure the novel food application. He had provided the required information of a non-GMO novel food. Concerning the compositional data, the applicant gave a typical compositional profile of the juice. He also had a Quality Assurance Policy and Procedure Manual to ensure the consistency of products. The samples used for toxicological tests were shown to be representative of commercial products.¹⁵¹⁶ The applicant had paid particular attention to finding possible toxic chemicals, and found nothing.¹⁵¹⁷ The production process did not give rise to any concerns: it was similar to all fruit juices¹⁵¹⁸. Nutritional facts were also not particularly interesting: the juice is similar to other fruit juices¹⁵¹⁹. The microbiological issues were also the same as with other fruit¹⁵²⁰.

The extent of toxicological and allergy-related data is what separated the Noni application from Stevia and Nangai applications. There was ample data available on Noni.

¹⁵¹² Opinion of the Scientific Committee on Food on Tahitian Noni® juice (expressed on 4 December 2002). SCF/CS/NF/DOS/18 ADD 2 Final 11 December 2002.

¹⁵¹³ Commission Decision 2003/426/EC of 5 June 2003 authorising the placing on the market of 'noni juice' (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient (*notified under document number C(2003) 1789*).

¹⁵¹⁴ Opinion on noni fruit as novel food, page 2.

¹⁵¹⁵ Opinion on noni fruit as novel food, page 3.

¹⁵¹⁶ Opinion on noni fruit as novel food, page 3.

¹⁵¹⁷ Plants such as *Morinda Citrifolia* were known to have chemicals called anthraquinones in their roots, and these chemicals were known to be genotoxic. It had been stated in a previous study that these chemicals did not exist in the fruit of the plant. Still, the applicant had analyzed the juice for these chemicals. Opinion on noni fruit as novel food, page 3.

¹⁵¹⁸ Opinion on noni fruit as novel food, page 4.

¹⁵¹⁹ Opinion on noni fruit as novel food, page 5.

¹⁵²⁰ By applying Good Agricultural Practices (GAP), Good Hygienic Practices (GHP), Good Manufacturing Practices (GMP) and pasteurisation (87.7 °C for three seconds) the product was to be regarded as microbiologically safe. Opinion on noni fruit as novel food, page 5.

The history of use for Noni is interesting. The plant occurs from India through South-East Asia to Eastern Polynesia. It has a long tradition as dye plant¹⁵²¹, as medicinal plant and as food. Virtually all parts of the plant (fruit, leaf, bark, root, flower and seed) have been used *for medicinal purposes* such as to treat cuts, inflammations, fungal infections, constipation and diarrhoea. *Food use* also has a long history: several studies refer to raw or cooked Noni fruit as part of the diet of aboriginal populations of Polynesia and Australia. Some studies suggest that it was eaten only in times of famine, as it tastes and smells bad.¹⁵²² “Tahitian Noni” juice was at the time of the application already produced on a commercial scale. The applicant had marketed its “Tahitian Noni” juice in USA, Canada, Japan, Australia, Mexico, Norway and Hong Kong.¹⁵²³

Lessons of the Noni, Stevia, and Nangai cases

Based on the information on two prohibited products, particularly Nangai nuts, it is not enough that the products seem to be safe, based on thousands of years of use. You also have to prove it by various tests. The list of required information in the Commission Recommendation should be considered mandatory. As all of the above-mentioned tests are required before you can bring a food on the market, it is fairly demanding particularly for a small company.

It is also noteworthy that in the noni case the Member State would have been stricter, and in the nangai case, the Member State would have been more flexible than the Scientific Committee of the European Commission. In the current system, Member State opinion is thus not a good predictor of the final outcome of the procedure.

Based on the above cases, we predict that emblic leafflower or products made thereof could probably receive novel food authorisation, provided that we performed all the required tests on toxicology and nutritional values.

6.6.2 Future EU Novel Food Regulation

To get a better picture of the novel status of our potential products, we must look into the proposed changes in the EU novel food regulation. In the future, the producers will hopefully not have to avoid the novel food category. The Commission has proposed changes to the definition of novel food, to the novel food process, and to the nature of novel food decisions as to whom they apply. We cannot be sure whether the Commission proposal will be accepted as such, but we have chosen to discuss some of the likely issues that might affect our types of product.

It is very probable that the European Food Safety Authority (EFSA) will evaluate novel food applications in the future. This has also been supported by the majority of stakeholders. EFSA will have all the best experts to evaluate the safety. The Commission has proposed novel foods to be evaluated in the Common Procedure that is also applicable to additives, flavourings, and enzymes. In this procedure, the application for authorisation is sent to the Commission, which hears EFSA, and publishes a Community list of authorised foods. Timelines are set for each stage of the process.

¹⁵²¹ Its root and bark have been used for colouring purposes. Opinion on noni fruit as novel food, page 4.

¹⁵²² Opinion on noni fruit as novel food, page 4.

¹⁵²³ Opinion on noni fruit as novel food, page 2.

We have previously predicted that emblic leafflower fruit would currently be regarded as novel food in Europe. This would also apply to some other Chinese berries and plant-based products. The *novel food definition* is not about to be changed. As a result, in the future the so-called exotic plants will still be considered novel in the EU.

Instead, the authorisation procedure will be made less stringent and more affordable for plant-based products than for those more technological novel foods. It has been proposed that a simplified procedure will be applied to traditional foods from third countries. This change is welcome by several actors, and will make the situation a bit more convenient for importers of foreign berries, fruit, vegetables etc. The primary procedure has been considered too burdensome, and also as a restriction of trade for exotic fruits.

In the future a notification procedure shall apply to our products, more particularly functional foods made of emblic leafflower fruits. According to the proposed Novel Food Regulation, “traditional food from a third country” means “novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least one generation in a large part of the population of the country”.

A marketer of a traditional food will still have to provide some evidence on safety. The notification shall be accompanied by *documented data* demonstrating the history

of safe food use in the third country¹⁵²⁴. We will need a certificate of the foreign, in this case Chinese, food safety authorities stating that the product has been used for a long time without any safety issues arising. “History of safe food use” indicates that “the safety of the food in question is confirmed with compositional data *and* from experience of use *and* continued use in the normal diet of a large part of the population of a country”¹⁵²⁵.

In the future novel processes leading to a significant change in food composition or structure will still be evaluated according to the EU novel food regulation.

6.6.3 Chinese Novel Food Legislation

In China, a functional food ingredient might have to go through novel food legislation. A novel food might be for example a foreign plant, a newly developed raw material, or an innovative processing technology. The novel food procedure does not have anything to do with health claims. One must always go through the health food procedure if one wishes to present health claims on the final product.

The Chinese novel food legislation will not affect our business because the three berries have established food uses in China. This makes them non-novel. For example, wolfberries are added to congee soup¹⁵²⁶, and hawthorn is used in haw flakes¹⁵²⁷. Emblic leafflower is not as common in China as in India, and is mainly used in China as a health food supplement, which still accounts as food use and makes the berry non-novel.

¹⁵²⁴ Article 8(1) of the Novel food proposal 2007.

¹⁵²⁵ Article 3(2)(c) of the Novel food proposal 2007.

¹⁵²⁶ Wolfberry is also added to tonic soups, and used for as herbal tea. Even wolfberry beer is available. Wikipedia. Article on wolfberry.

¹⁵²⁷ Haw flakes are a Chinese sweet made of hawthorn. Hawthorn is also used in jams, jellies, juices, alcoholic drinks etc. Wikipedia. Article on Crataegus.

6.7 General Rules on Marketing

6.7.1 EU

A functional food marketer must keep in mind the general rules on advertising and comparative advertising: giving false or misleading information to consumers is prohibited, and applies both to foodstuffs and medicines.

Foods must be labelled so the consumer is provided with all the information required by the labelling rules. The newest labelling requirements relate to common allergens. Nutrition labelling is currently mandatory if a nutrition claim is made, and otherwise voluntary. Novel foods and GMO foods have their own labelling requirements. European consumers are hesitant to purchase GMO foods.

For food supplements consisting of *vitamins or minerals*, the EU regulation of 2002 applies. The regulation includes specific labelling requirements. Consistently with the food supplement legislation, rules on foods fortified with *vitamins or minerals* are harmonised in Europe (since 2004). Also for fortified foods, there are specific labelling requirements. For other supplements and other kind of fortification, such as products with fibre, amino acids or herbal extracts, national rules apply. We predict that European harmonisation of supplements and fortified foods will continue in the future to cover these other types of common products.

We are mainly interested in functional foods, referring to foods that are in food form and possess some health effects. Some of these might be fortified as discussed above. One marketing alternative is to sell the product as a *dietetic food*. For dietetic foods, (foodstuffs for particular nutritional purpose), the word ‘dietetic’ or ‘dietary’ can be used. Dietetic foods are always aimed for specific groups of people with specific dietary needs. Some dietetic foods involve pre-market notification. For dietetic foods, nutrition labelling is mandatory.

A *nutrition claim* on a food is basically a claim where the amount of a certain nutrient is claimed to be high or low. For example, ‘low fat’ and ‘high fibre’ are nutrition claims. Nutrition claims are legally a fairly simple question as all allowed nutrition claims are listed in the Annex of the nutrition and health claim regulation of 2007. One just needs to be aware (to measure) the content of the substance, for example fat, in the product. Health claims on foods will be separately discussed in the next chapter.

At least in theory, functional foods could also be sold and marketed as medicines, as discussed above. In this case, the product must comply with rules on medicine labelling and advertising, and restrictions to marketing channels. All medicinal products must include a package leaflet in their packaging, and the information to be given on this package leaflet is precisely regulated. For example instructions for proper use and information on medicine’s side effects are important for consumers. All medicine marketing must encourage rational use of medicines. Medicine advertising must not be directed at children. Prescription medicines cannot normally be advertised. Medicinal claims will be separately discussed in the next chapter.

6.7.2 China

The Chinese general rules on marketing are largely the same as in Europe. The aim is to provide the consumer with all the relevant information of the product. Misleading advertising is prohibited.

Foods must be labelled. Particular requirements on allergy labelling are still missing. Medicines must have a product leaflet containing all the relevant information on the product.

In China, it is not so much the marketing legislation but its implementation that is lacking. Because of severe scandals related to counterfeit and fake medicines, the Chinese are now focusing on control and supervision of the rules on medicine advertising.

6.8 Legislation on Health Claims and Medicinal Claims

Above we have discussed whether our fictional functional food products would be regarded as foodstuffs or medicinal products. *Here we assume that some of our final products are legally medicines, and some are foods.* We have developed products in different legal categories and we want to make marketing claims that are as convincing as possible.¹⁵²⁸ Thus, we are willing to present health claims for food products, and medicinal claims for medicinal products.

The viable legal categories within the EU are¹⁵²⁹:

- (traditional) herbal medicinal product,
- dietetic food (foodstuff for particular nutritional purposes) and,
- as the most interesting alternative, *a ‘normal’ food with health claims*

A dietetic food could be sold as a food suitable for diabetics or a food suitable for people with high cholesterol or hypertension. The normal food with health claims could be aimed for example at people with a risk of diabetes or cardiovascular disease.

The viable legal categories in China are:

- traditional Chinese medicine, and
- as the more interesting alternative, *health food.*

6.8.1 EU

The first rule concerning claims is that *medicinal claims on foods are prohibited.* This applies to all foods including normal foods, dietetic foods and food supplements. Medicinal claim means a statement where a product is said to prevent, treat or cure a disease.

Health claims on foods are legal but subject to stringent requirements. There are two types of health claims, so called ‘function’ claims and disease risk reduction claims. The Commission will publish *EU wide lists* on both types of accepted health claims.

¹⁵²⁸ In reality, we would consider the claim issue simultaneously with the safety issue and all the other aspects of product development. In this study, the marketing issue is discussed separately for readability reasons only.

¹⁵²⁹ Here we have left out the option of developing a ‘normal’ medicinal product. This would mean finding and capturing the active chemicals in the plants, and selling them as (prescription) drugs. It is not certain that this kind of medicinal product could ever be developed and authorised, and it would take years if it were possible. In this study, we are interested in the mass consumer market, and primarily products sold by the food industry. Herbal medicines (in Europe: herbal medicinal products, in China: traditional Chinese medicines) are included, because the legal division between herbal medicines and functional foods is important, and some food-form products might be legally categorised as herbal medicines, regardless of whether intended as such.

The EU Member States are currently preparing their lists on established 'function' type health claims. These lists are to be submitted to the EFSA by January 2008. Industry consultant Richardson advised companies to find out what is on the Member State lists. Accordingly, if a food is not on the positive list by 2010 hard work will be required for a claim to be made in the future¹⁵³⁰. At this stage, we cannot be sure what claims will be on the 'established claim' list. It is unlikely that claims particularly on emblic leafflower, barbary wolfberry or even the more familiar hawthorn will appear. The final list will most likely include antioxidant claims such as claims on flavonoids and phenolic compounds¹⁵³¹. These substances are present also in our berries, which will make claims similar to "contains antioxidants" available to us.

Novel health claims (claims not on the list) and disease risk reduction claims must be authorised separately. We would be interested in claims that maintain: "For sufferers of metabolic syndrome", "Lowers cholesterol", "Lowers blood sugar", etc. We could either state that "Hawthorn lowers cholesterol", or that "Functional food product Hawthorn lowers cholesterol". The rules are the same. The claim must not be misleading: the active ingredient must be present in quantities that produce a health effect in normal use. The scientific assessment of a disease risk reduction claim is made by EFSA, and the final decision by the Commission. With disease risk reduction claims, one has to keep in mind that the risk factor itself might not be established. In this case, initially it needs to be proved that a certain condition is a risk factor, and then that the product affects the risk factor.¹⁵³²

The EU Regulation on nutrition and health claims came into force in 2007. It is interesting that Commission claimed to create liberal legislation:

"The proposal covers nutrition claims (e.g. "rich in vitamin C" or "low in fat") and health claims (i.e. claims of a positive relationship between a specific food and improved health). It sets rules for making such claims and also allows health claims (including "*reduction of disease risk*" claims) that *were previously prohibited*. In the interest of consumer protection, it also includes certain restrictions. The Regulation will protect consumers, improve the free movement of goods, increase the legal security of operators and prevent abusive claims, thus ensuring fair competition. The proposal will result in *a more liberal environment* for claims in labelling and advertising. Disease-related messages, which were until now totally prohibited by EU legislation, will now be allowed if they can be scientifically substantiated and authorised at EU level."¹⁵³³

The Commission seems to state that health claims were previously prohibited and that now they have been freed. In fact health claims were not prohibited before the regulation. In several countries they were allowed, including disease risk reduction claims. The food industry does not see the new regulation as making the situation more liberal; in fact they see the Regulation as one of the strictest possible alternatives of the various systems available.

¹⁵³⁰ Nutraingredients.com news at: <http://www.nutraingredients.com/news/ng.asp?n=76579-efsa-health-claims>.

¹⁵³¹ See for example the Finnish list of 'function' claims, and particularly the list of antioxidant claims Ministry of Trade and Industry web page at: <http://www.ktm.fi/files/18357/Antioksidatiivisuus2.pdf>.

¹⁵³² Heiskanen 2001, 26.

¹⁵³³ Commission DG SANCO Food Safety web page 21st September 2006.

What is positive to a functional foods developer is that legal uncertainties around the claim issue seem to be resolving, at last. The lists of established claims are impending and there is plenty of guidance available on how to use claims. Nutrition and health claims are factual claims that have to be substantiated, which is not too much to ask from every responsible business. There are procedural costs with new claims, but they affect the competitor similarly. The choice by an entrepreneur of a nutrition or health claim will depend on the costs and benefits of the claim.

Companies view health claims as a means of recouping some of the financial outlay for testing of efficacy and toxicity of the products. The possibility of making claims encourages investment in product development and introduction and export of new innovative products.¹⁵³⁴ Claims are useful to the company if they are useful to the consumer. Incidentally for some, claims on labels may be the only way to obtain knowledge of healthy products.¹⁵³⁵ The consumers will decide on their own if they want the product, based on many other factors besides the claim¹⁵³⁶.

It is not necessarily always clever to make a health claim just because it is legally possible. Costs in making claims relate to chemical analysis¹⁵³⁷, human studies¹⁵³⁸, and submission of the evidence to the regulatory authorities. The new regulation rewards these efforts by granting five-year exclusivity to proprietary materials that support a health claim. After this period, competitors can use the proprietary data without compensation to the originator.

¹⁵³⁴ For example Suontama 1999, 26, and Tainio 1997, 40.

¹⁵³⁵ For example through the Kellogg's All Bran campaign in the USA, knowledge of the relationship between fibre and cancer increased, with the greatest change in those socio-economic groups that do not read educational material. There may, therefore, be an advantage to claims of packaging for those sectors. Stephen 1998, 432. Even in Finland, there are people who never read a magazine on health. Those that are still in school may have up-to-date information on nutrition, but others do not go to lectures on newest nutritional research.

¹⁵³⁶ For example the sensory properties of the product, the price of the product, personality, age and social class of the consumer, etc.

¹⁵³⁷ Analytical procedures appropriate for determining concentrations of chemical entities within products include gas chromatography, high-pressure liquid chromatography or thin-layer chromatography. Many of the methods are time-consuming and hence costly, but it is unlikely that once the method is developed and validated, the results would be ambiguous. Stephen 1998, 429.

¹⁵³⁸ With human studies, a considerable financial commitment can be incurred in a study for which the results are not even useful. All efforts should be made to determine that results would be meaningful and unambiguous before substantial costs are incurred. According to Stephen, embarking on the production of new products without recognising the requirement of scientific proof of effect as a component of the overall development of a product is a recipe for failure. There are many who believe that a little rapid research is sufficient to confirm the reputation of a plant, and then attempt to proceed from there toward lucrative industrial production. Stephen 1998, 429.

Scientifically, it is not always easy to manufacture a product that justifies a claim¹⁵³⁹. Some studies show¹⁵⁴⁰ that some consumers do not want health claims, as they do not have faith in them. In spite of strict legislation, these consumers might still exist. Sometimes consumers first resist a claim, but then learn to accept it¹⁵⁴¹. In some countries, functional foods are sold where claims are not permitted, or outside the health food categories. This means health claims are not the only way to success.¹⁵⁴²

It is also noteworthy that the new regulation on health claims only allows health claims on foods where *the nutrition profile* of the food is in certain limits. These nutrition profiles will be established for different foods, such as breakfast cereal and yogurt. This will be done by the EFSA by January 2009. The profiles will include limits for different types of harmful fats, salt/sodium, and sugar. This means that a barbary wolfberry yogurt or an emblic leafflower muesli with a health claim cannot contain much sugar or fat. The functional food product must be healthy as a whole.

There is one exception to the nutrient profile rule. If the product only exceeds one single limit in the nutrient profile, it can still be presented in a nutrition claim of the product that another nutrient is present in low quantities. For example, a yogurt can be claimed to be 'low-fat' even if it has lots of sugar. In this case, a statement 'high in sugar' must be included along with the 'low-fat' statement. As we are interested in health claims, and not so much in nutrition claims, this loophole does not aid our case.

Medicines always bear a medicinal claim, as they must have a *therapeutic indication*. The therapeutic indication is the key of the whole product, and also the key of consumer marketing. The therapeutic effect of a *herbal medicine* is typically verified by literature instead of scientifically verifying it in animal tests and human trials. With *traditional herbal medicines*, not even literature evidence is required. However, traditional herbal medicines are

¹⁵³⁹ Bioavailability and performance of the active ingredients is not always a simple thing. For example, vitamin supplementation often fails, and many vitamin-enriched prototypes contain too little vitamin compared to planned claims. Vitamins C, thiamine and riboflavin are particularly unstable and difficult to work with. A food company might need to partner with someone with medical insight and ability to do clinical trials. For this reason, specialist research companies and the pharmaceutical giants are partnering with food ingredient supplier and food companies. Food Engineering & Ingredients, October 2001, 18.

¹⁵⁴⁰ There has been consumer research showing that consumers want strong claims, and research that shows they don't. Niva and Jauho (1999) found a connection between a consumer's perception of research on diet-health relationship and his perception of health claims. If the consumer generally is suspicious of health effects of single products, he does not want health claims – because he thinks they are misleading. Those consumers that have faith on scientific research behind functional foods are in favour of the use of health claims in marketing. Niva – Jauho 1999, 46-47. This means that if you do not already have the trust of the consumer, claims will only create adverse reactions.

¹⁵⁴¹ Young 1998, 173.

¹⁵⁴² For example in Japan, the population accepts the functional benefits and is knowledgeable about them, and thus they will buy the products independent of the claims. While a considerable number of products have been licensed FOSHU (food for special health use) in Japan, this is a small number in comparison to the hundreds of functional products being successfully marketed in Japan. Stephen 1998, 431. With olive oil (particularly in the United States), the findings on its healthiness were reported at scientific meetings, in the literature, and from there to the popular press and media. The result was a huge increase in sales of olive oil. Without the ability to make a claim, the olive oil industry is benefiting through good research in the form of controlled human studies. The findings are sound, unambiguous and have been confirmed by a number of investigators worldwide. Stephen 1998, 432. This implies that if the scientific proof is widely known and trusted, claims are not necessarily needed.

not allowed to contain mention of a therapeutic indication. These products are allowed to be sold as medicines, but without medicinal claims.

All of the three berries have potential for developing herbal medicinal products. With adequate evidence, these products could be authorised through the primary procedure for medicines. Hawthorn has established use as herbal medicine in Europe, but the traditional herbal medicine option is probably still not available. Only those products that cannot be registered as herbal medicines are allowed to be registered as traditional herbal medicines. The category of traditional herbal medicines is for plants on which information is not available, and on hawthorn there is both literature on traditional use and data from newer scientific studies. We would not be interested in the traditional herbal medicine category anyway, because we want to present strong claims.

6.8.2 China

Health foods and drinks became big business in China during the 1990's. The market grew chaotic which led to government intervention. With the enactment of the health food regulation in 1996, the number of producers of health foods decreased to less than a third in less than a year. The rigid regulatory environment allows genuine manufacturers to recoup market share and gain a certain critical mass. Simultaneously to promoting domestic research and development, the Chinese laws have also gradually opened the market to foreign health products and ingredients.¹⁵⁴³

According to Chinese legislation on health-related products, the name of a product must not be misleading or confuse foodstuffs with medicines. Medicinal claims are allowed for medicinal products only, including traditional Chinese medicines. Medicinal claims are prohibited on foods. *For health foods, and only for health foods, health claims are allowed.* Among the 27 listed possible health food functions, at least 3 are quite suitable for our purposes. These are:

- assisting in blood lipids reduction,
- assisting in blood sugars reduction, and
- alleviating hypertension.

If we have the required scientific evidence on our products, we can apply for health food status for our functional food products. The claims on health foods must be truthful, and substantiated through animal tests and/or human trials. The SFDA is responsible for pre-market approval of health foods. Only the listed 27 claims are available. Other health claims are prohibited.

There are important restrictions to health food raw materials. There are three categories of raw materials with three lists.

- List I includes materials that can be used either as foods or medicines (around 90 substances).
- List II includes materials that can be used as health food materials (around 110 substances).

¹⁵⁴³ Giract China News February 2006. Extract in Functional Ingredients.

- List III includes materials that are prohibited as health food materials (around 60 substances).

First of all, one can use only 14 different raw materials in one product. This figure includes health-promoting materials and not basic food raw materials such as water or sugar. Furthermore, if one uses materials outside list I, one can only use 4 materials altogether. If one uses materials outside lists I and II, one can only use 1 raw material.

Hawthorn and barbary wolfberry are on the first list. This means that if we use hawthorn and barbary wolfberry, we can also use 12 other raw materials (that are not on lists 2 or 3). For example, if we want to use hawthorn with one material on the list II, for instance Ginseng fruit, we can use 4 materials altogether. Emblic leafflower is not on any of the lists. This means we can use it as health food raw material, but in this case we cannot use other raw materials.

6.9 Other Legal Issues to Consider

When using plants as raw materials in functional foods, food supplements or herbal medicines, one has to make sure that it is not a question of *endangered species*. CITES (the Convention on International Trade in Endangered Species of Wild Fauna and Flora) applies here. Practically all countries are parties to CITES. The EU has even stricter rules than CITES on international trade of endangered species.

Intellectual property issues are obvious to pharmaceutical companies but they also apply to herbal medicines and functional foods. It is often advisable to protect the functional ingredient by a patent or a utility model, and the names and logos with trademarks. Trademarks have to be registered for every country separately. The cost of trademarks rises with the number countries, the number of product categories, and the time of exclusivity. Sometimes the protection for geographical origin of the food might be relevant. Poor enforcement on intellectual property rights remains a top concern for companies operating in China. It might influence research and development plans, and the products or technologies that companies are willing to sell, license, or manufacture in China¹⁵⁴⁴.

Contracts form the framework for business. Confidentiality agreements with international business partners are needed. Sometimes keeping the information secret is a better alternative to disclosing the information in a patent application. Patented ingredients or other property material or knowledge may be commercialized by licensing agreements. With international contracts, the choice of law and the venue for dispute settlement are things to consider.

6.10 Final Conclusions for a Functional Food Marketer

When developing functional foods, legal issues including marketing rules must be considered in early stages of product development. Legislation is not necessarily something that hampers good products from achieving the market but a reminder of issues that a responsible producer would have to consider anyway. A good product is something a consumer can trust. It delivers what it promises. It is up to the manufacturers to know and decide which regulatory category their functional food will fall into. The choice of legal category should be compatible

¹⁵⁴⁴ See US-China Business Council 2008, 12.

to the scientific proof of effect, and a claim requires a complete and integrated marketing communications plan around it.

A product will be classified as medicine in Europe, if one uses medicinal claims such as “prevents heart disease and diabetes”. A product will also be classified as medicine, if functional ingredients are present in quantities that cause a pharmacological effect. With plant-based products, one possibility is to consciously sell the product as herbal medicine. Traditional herbal medicines can be sold based on history of use only, without having to prove efficacy. If sold as food, an innovative product must probably be authorised through novel food procedures. This requires explicit microbiological, nutritional, and toxicological data to be joined in the application. The European definition of novel food includes all the plants that are unfamiliar to Europeans, even if used for centuries for example in China or America.

As regards marketing in Europe, foods are allowed to bear health claims but not medicinal claims. Functional foods could be sold as dietetic foods, foods that are suitable for certain groups of people, such as for people with celiac disease. Concerning foods with a more general target group, nutrition claims and health claims can be used according to the new European Regulation. A list of established ‘function’ claims will be published in 2010, after which all new ‘function’ claims must be authorised separately. Disease risk reduction claims will always have to be authorised separately.

According to Seppänen, the false orientalist picture of China as a lawless Confucian society has led to foreign companies neglecting legal planning in China¹⁵⁴⁵. We do not want to do this mistake. In China, foodstuffs and medicines are separated by their functions and claims just as in Europe. Medicines have therapeutic effects, and only medicines are allowed to bear medicinal claims. The health food category is often suitable for a functional food, if it has one of 27 listed functions. Only health foods can bear health claims in China. The health food regulation also covers foods fortified by vitamins and minerals, and vitamin and mineral supplements. The novel food category and the health food category are separate in China: a food cannot be both. This means that if health claims are wanted, both safety and efficacy of the food are evaluated through the health food procedure.

¹⁵⁴⁵ Seppänen 2005, 584.

7 TASKS OF FUTURE LAW

In this chapter, we draw conclusions on the European and Chinese legal systems from a regulator's perspective. The laws on foodstuffs and medicines will constantly have to be re-evaluated and further developed in both the EU and China.

7.1 Foodstuffs vs. Medicines

In China, the foodstuff vs. medicine -issue is actually not an issue. The same product, often a herb, can be sold as food for healthy people and as medicine for sick people. Health foods often comprise of materials that are used in traditional Chinese medicine. The legal difference between health foods and medicines is that *health foods have a special health function, but are not for curing a disease*.

The European legal definition of food encompasses products ingested by humans, excluding medicines. This means the food law does not give any clarification to whether a borderline product should be treated as a medicine. We have to look at the definition of medicine. The Medicinal Products Directive gives two parts to the definition of a medicinal product, by virtue of its presentation and by virtue of its functions. Consequently, a product is legally a medicinal product if it falls within either or both of these parts. This principle has been consistently held and confirmed by the European Court of Justice. The definition of medicinal product was recently changed. It was clarified that *medicinal function means pharmacological, physiological or metabolic action*¹⁵⁴⁶, whereas according to the Nutrition and Health Claim Regulation, foods might have “beneficial nutritional or physiological effects”¹⁵⁴⁷. It was also added into the Medicinal Products Directive that *all unclear cases are to be regarded as medicines*.

From the EU definitions of food and medicine, it is still not clear whether a functional food could in practice be authorised as a medicine. As described above, the definition of medicines is fulfilled if the product either A) has a medicinal effect or B) uses medicinal claims. There are no other parts to the definition. There is no exclusion of foods. It is clear that according to law, a functional food (as defined in chapter 1.3.) could be considered a legal medicinal product or an illegal medicinal product either by its functions or by its presentation. In practice, food-form products are rather classified as foods.

¹⁵⁴⁶ Directive 83/2001/EC, Article 1(2).

¹⁵⁴⁷ Regulation 1924/2004/EC, preamble 14.

The borderline between foodstuffs and medicines remains a problem, as the European Court of Justice has accepted that there can be different interpretations of the definition of medicinal products among the Member States. A product can be a food in one Member State and a medicine in another. Herbs in particular are often used both as foodstuffs (food supplements, natural sources of food flavourings) and as herbal medicines¹⁵⁴⁸. This is one remaining obstacle to free movement of foodstuffs and medicines.

In the future, it is possible that:

- there will be a European law on how to divide products into foodstuffs and medicines,
- the categorisation decision will be done by the EFSA, and it will be applicable to the whole Community.

The UK experience with guidelines and procedures for borderline products could be used as guidance in establishing a similar categorisation system at the European level¹⁵⁴⁹. The function and the claim of the product would be evaluated together to determine whether a product is a medicine. If a product contained *therapeutic doses of ingredients generally regarded as medicinal and indicative of a medicinal purpose*, it would likely be considered a medicine. With regard to presentation, a UK-style list of phrases forbidden in food marketing could be useful to marketers¹⁵⁵⁰. If the division between foodstuffs and medicines is considered necessary, the European definitions should be unambiguous.

Even if we create efficient categorisation rules, it will take a lot of the entrepreneurs' and the agencies' energy to determine whether a product is a food or a medicine. The European legislators tried in 2004 to make categorisation easier by establishing the unofficial borderline category for "unclear cases", and directing these products under medicine law¹⁵⁵¹. The difficulty of defining medicines in manner that would clearly exclude foods could also have lead legislators to the conclusion that *the categorisation decision should not be decisive*. Nutrition and health are closely connected, and science reveals new connections all the time. We might just as well classify all foods as medicines. Our science-based understanding on the relationship between diet and health seems to make it impossible to define medicines in a manner that would clearly exclude foods.

Instead of focusing on what is food and what is medicine, legislators should focus on safety and efficacy of all products. If borderline products do not fit to the two sets of rules (one for foodstuffs and one for medicines), there are basically two alternatives. Either we create a borderline category or we bring regulation of foodstuffs and medicines closer together. If similar principles are used with foodstuffs and medicines, similar products are treated in similar manner, regardless of the classification decision. This way the classification decision could no longer lead to great injustice.

We can already see the regulation of foodstuffs and medicines coming closer together. The novel food legislation and the health claim legislation together are creating a kind of authorisation

¹⁵⁴⁸ Silano et al. 2004, 108.

¹⁵⁴⁹ The UK rules on borderline products were discussed above in chapter 3.

¹⁵⁵⁰ Including marketing terms like "alleviates", "avoids", "clears", "combats", "controls", "counteracts", "eliminates", "fights", "heals", "help", "protects against", "remedies", "removes", "repairs", "restores", "stops", and "traditionally used for".

¹⁵⁵¹ See Directive 2004/27/EC, Article 2(2), and explanations in preamble 7 of the Directive.

procedure for functional foods. Both evaluations (safety and efficacy) are in the future done by the EFSA. This evaluation is similar to what the EMEA is doing with medicines. Similar principles are used in evaluating plant-based novel foods and herbal medicines.

From consumer point of view, the purpose of use of a product is decisive. It is not important whether a product is a food or a medicine but whether it has a health-enhancing function or a medicinal function. There will be products with health effects (weight-loss products, lactose-free, gluten-free products, products for diabetics, products with added or concentrated vitamins, minerals, prebiotic or probiotic acids, fibre, herbs, sterols and stanols, xylitol, etc.), and products with medicinal effects (herbal and chemical medicines). The claim will inform the consumer on the purpose of use, and the use of a health claim or a medicinal claim will depend on scientifically proven effects of the product. *The product form (food vs. pill) should not be legally relevant.*

Food supplements seem to be a somewhat obscure, suspicious and problematic category for everyone involved: some marketers try to sell the products as medicines, some consumers use food supplements for medicinal purposes, and authorities take the product form as a medicinal message. The legal concept of food in concentrated form does not seem to reach the audience. We suspect this is due to the fact that food supplements in practice always do have special health effects, separating these products from common foods (foods in food form) and bringing them closer to medicines. Instead of what the product is (food vs. medicine), *it is interesting what the product does.* Some products have health effects and some products medicinal effects.

This brings us back to making *the distinction between disease risk reduction and disease prevention.* It might be impossible to reach a situation where all the stakeholders, including the consumers, understand and agree on these two concepts. Regardless of all the legal determinations, classification rules, and scientific criteria, European and Chinese consumers can still use foods for medicinal purposes. This is something the law cannot affect. Consumers can also use spells, rocks, crystals, scents, flowers, etc. for medicinal purposes. The legislator can give precise criteria for authorising products, but cannot force consumers to trust them, or to distrust something else.

7.2 Law on Product Safety

7.2.1 Food Safety

Food safety law is complicated with several different factors of safety to consider. Biological hazards like animal diseases must be rigorously fought against. Minimising the amount of harmful chemicals in food is also an important goal. Here we have mainly discussed the particular safety issues of functional foods, which are often related to novelty of the ingredients.

The aim of *novel food legislation* is that previously unknown substances cannot be put to consumers' dinner plates before pre-market scrutiny. Novel food legislation has existed in the EU since 1997 and in China since 1990. China revised its Novel Food Regulation in 2007. Also in Europe, novel food legislation is under reconstruction in order to deal with problems with the current law. In 2008, the Commission has proposed a new Novel Food Regulation. Currently, many companies wish for their products not to be considered novel. They might

even be deterred from product development that might result in something considered novel. This is because the novel food process is seen as excessively burdensome and unpredictable. Even if the product is clearly novel, illegal marketing of the novel food is often preferred to making an application.

The European food industry has called for a more *innovation-friendly* regulatory environment. The uncertainty of the legal status of novel products and possible delays in the novel food procedure exacerbate risks and add costs. The current novel food regulation rewards for being the follower to the market rather than the innovator¹⁵⁵². According to Brookes, the time taken for novel food authorisations should be reduced and uncertainties should be minimised. It is fairly easy to agree on these notions. Brookes is also of the view that incentives to encourage innovation should be considered either in form of exclusive access to market or compensation for data provision.¹⁵⁵³

With reference to *the European definition of novel food*, the issue of plant-based products raised controversy. The definition says all food not used in the Community before May 1997 is novel. This means that not only foods that are novel in the sense that they are newly developed are considered novel. Also foods, which have been used for perhaps thousands of years but which have not been used in Europe, are considered novel. The definition of novel food is clearly discriminatory and not based on science but instead on practical reasons. It is difficult to be aware of all the foods used in the world, so it was considered the most feasible to require documentation on all third country foods.

Novel foods must go through the pre-market authorisation procedure, where the marketer must present scientific tests and trials, indicating product safety. Foods that are equivalent to previous foods are exempted. This means old foods are presumed safe, and the novel food evaluation is mainly *a comparative test*. This comparative approach has been chosen because it is fairly difficult to prove absolute safety of a novel food, because a novel food often replaces something else in the diet and consists of multiple substances the effects of which are difficult to show in animal tests.

Third country food producers are understandably not so impressed on the justification behind the definition, or the rule that equivalent products are exempted. There have been continuous arguments at the WTO on the European novel food regulation, particularly regarding plant-based products from third countries. With plants, the Commission will have to decide whether 'history of safe food use' in the country of origin could be enough to presume the food safe. This decision will affect farmers in developing countries, and companies willing to introduce plant based products, such as functional foods made of Chinese berries.

Also, the Chinese definition of novel food is based on local novelty, not global novelty. Everything not traditionally eaten in China is considered novel according to Chinese food law. Each legislator has as its primary task to protect its own citizens. This should not, however, be used as an excuse to create artificial barriers to trade. The producers of exotic food products have strong arguments supporting their view that either at least some of their products *should*

¹⁵⁵² Brookes 2007, 6. Under the current Novel Food Regulation, other companies can obtain authorisation to market similar novel products almost immediately after the original applicant. Companies second to market companies avoid some of the costs associated with seeking authorisation. Companies 'second to market' are also not subject to the same time delays as original applicants in terms of planning market entry. Brookes 2007, 4.

¹⁵⁵³ Brookes 2007, 6.

not be considered novel, or, alternatively, that the safety requirements including scientific evidence and the authorisation processes should be less burdensome for these products.

To respond to the criticism, the European Commission has indeed proposed a simplified novel food procedure for traditional foods from third countries. Traditional foods are still defined as novel, but they need not show all the evidence on safety that is required in the primary procedure. The marketer is still required to provide the proof on history of safe food use. This means he will have to provide the Commission with compositional data in addition to evidence on long-time food use that still continues in the third country in question.

Novel production processes will continue to be evaluated under novel food law, if they lead to ‘significant changes’ in the food product. Despite criticism, the Commission has not in its 2008 proposal clarified the concept of ‘significant change’. This leaves room for soft law guidance. According to the current and the proposed Regulation, a novel process is evaluated under novel food legislation, if that production process “gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances”. According to Chinese novel food law, food ingredients are novel if their original composition has changed by the adoption of new production techniques. This newly introduced legal phrase will also require clarification on what is considered a significant change.

The issue of *food ingredients with multiple purposes* will be partly settled by the Commission’s proposal. A novel substance could be used as an additive or as an ingredient in other foods. A producer will in the future be able to apply for authorisation in one procedure instead of two procedures. In 2006, the Commission has proposed a Common Procedure for additives, flavourings, and enzymes. In 2008, the Commission proposed to include novel foods in this Common Procedure. If used both as an additive and an ingredient, the food can be authorised through one safety evaluation procedure. However, additives and ingredients have their own criteria according to which they are evaluated¹⁵⁵⁴, and if authorised, they are included in two separate Community lists. The Common Procedure does not apply to food supplements: they are still to be authorised in their separate procedure. Also in China, additives are regulated in a separate mechanism to novel foods. Food supplements are in China regulated either as common foods or health foods. If health foods, they must be registered as such.

The *property nature* of novel food authorisations is another important question to be answered. In addition to patents¹⁵⁵⁵, originator medicine companies enjoy data exclusivity, which is another type of intellectual property. The 10-year of exclusivity¹⁵⁵⁶ starts when an originator drug receives its license. During the exclusivity period, originator data cannot be used to authorise generic copies.

For novel foods, a similar type of intellectual property has been suggested in Europe. The suggested period of data exclusivity is 5 years. Novel food authorisations could be given as regulations that apply to all producers instead of decisions that apply just to the applicant.

¹⁵⁵⁴ The Additive Regulation vs. the Novel Food Regulation.

¹⁵⁵⁵ Patent protection is available for 20 years from the application. For medicines, this period can be increased by up to 5 years through a Supplementary Protection Certificate. Patents are also granted for new uses, indications, dosages, and changes in formulation. Producers or generics naturally think intellectual property protection for medicines is too strong. European Generic Medicines Association web page at: <http://www.egagenerics.com/gen-patents.htm>.

¹⁵⁵⁶ After 8 years, a generic producer may apply for authorisation. After 2 more years, the generic can be marketed.

Duplicating efforts will be avoided, and data exclusivity will be the reward for being first to market and completing all the necessary safety tests. The regulations authorising novel foods could apply to all different uses of the new ingredient. This relates to the above-mentioned question of possibly combining the additive, supplement, and ingredient procedures.

The benefit of the data exclusivity period would be simplicity. There are problems, though. If the definition of novel food would not simultaneously be changed, also data on third country vegetables and berries would be granted exclusivity. This would sound unreasonable. One could also argue that patent protection, or in some countries utility model, is enough intellectual property for food developers. For unpatentable foods, this approach presumes that trademarks are enough protection, and being the first to market is enough incentive.

In China, decisions on novel food authorisation apply to all, and there is no data exclusivity. Due to history and economic reasons, the Chinese are generally not in favour of strong intellectual property or granting private monopolies. Also in Europe, there is a strong movement against creating more property rights. In the future, new types of intellectual property will at least have to be considered in many fields of economy. They are suggested because old types of intellectual property are not deemed to serve their goals properly. Reorganisation might include making some property rights stronger and others weaker.

7.2.2. Medicine Safety

With regard to medicine safety, there are considerable gaps in knowledge as regards plant-based medicines. The utilisation of herbal medicine in the prevention and treatment of diseases and the maintenance of health is currently not fully realised, partly due to lack of rules. Herbal medicines are completely legal and increasingly popular also in Europe. However, the legislation is not based on any detailed knowledge on safety, efficacy or cost-effectiveness. Neither do European governments have clear strategies on how to develop the herbals industry and how to best guarantee consumers' rights. The European legislators' attitude towards herbal medicine is rather uninterested, even though the use of herbal medicine might often be an effective alternative with fewer serious side effects and lower cost.

With the creation of the category of traditional herbal medicine by Directive 24/2004/EC, the EU decided to step away from the evidence based approach and justify marketing based on use only. According to the rules, it is legal to sell a product as a traditional herbal medicine if it has been used for such purpose without side effects for at least 30 years, of which 15 years in the Community area. The EMEA Committee for Herbal Medicinal Products is currently drafting a list of plants that have established use as traditional herbal medicines. National registrations will be granted based on this list.

The decisive date with traditional herbal medicines is when the new law came into force. In Finland this was November 2005. The authorities look 30 years back from this date to determine the products that have been in use for at least 30 years. Any new products cannot after this require the status of traditional herbal medicines. This means that if the product has been used for thousands of years for example in China, it is not possible to acquire the European status of traditional herbal medicine. Traditional medicines of countries outside Europe must go through the primary procedure for herbal medicines.

China has in recent years considerably strengthened its medicine legislation. This process was related to China's entry to the WTO in 2001. Requiring GMP (good manufacturing

practice) certificates of all medicine manufacturers has significantly reduced the number of medicine manufacturers, thereby cleaning up the market. Counterfeiting medicines has been attacked with stricter legal consequences. However, more resources on medicine control are still needed.

The Chinese have a long tradition in using plant-based medicines, and traditional medicine is strong in China. The Chinese are researching medicinal plants and developing this industry side-by-side with modern medicines. After thousands of years of practice, the Chinese are also putting legislative effort into further developing traditional medicine. The Regulations on traditional Chinese medicine were given in 2003. In 2007, the Ministry of Health drafted a law that will specify the requirements on traditional medicine. The Chinese have strategies in place to integrate traditional medicine with modern medicine and ambitious goals in creating research protocols and post-marketing surveillance systems for traditional medicine. They see traditional medicine as globally integral in bringing health for all.

The Europeans might have something to learn from the Chinese approach where herbal medicine is taken seriously. The Chinese efforts will probably show in future global market shares of plant-based medicines. The potential of herbal medicine cannot be fully realised by settling for unscientific not to mention discriminatory regulatory solutions.

7.3 Law on Health Claims and Medicinal Claims¹⁵⁵⁷

Consumers are often ignorant of the nutritional basis underlying functional foods, and thus susceptible to betrayal. Marketing of functional foods must thus be regulated. With marketing of functional foods, the legislator's tasks are to guarantee adequate information to consumers and to protect them from misleading claims. At the same time, the industry must not be burdened with overly heavy obligations. With no regulation, functional foods backed by considerable research efforts and investment could be undermined by less effective products. This would be frustrating to legitimate businesses.

The European Regulation on nutrition and health claims¹⁵⁵⁸ is a huge step in regulating functional foods and hopefully cleaning up the industry. Before the Regulation, companies had too much space to confuse consumers with impressive but imprecise claims. Consumers were confused by all kinds of health claims, which were more or less scientifically substantiated, and the role of traditional foodstuffs became unclear. The Regulation was preceded by years of discussion, frustration, and national rules. According to Commissioner Kyprianou, each side would have liked to go further with the nutritional claim and health claim regulation, but the decided outcome is a good compromise that takes account of all positions in a balanced way.¹⁵⁵⁹

In the future, only foods that comply with a certain *nutrient profile* can bear claims. The EFSA will publish nutritional profiles for each product type by 19 January 2009. The nutritional profile requirement means that if a food is high in fat, saturated fatty acids, trans-fatty acids, salt/sodium, and sugar, it cannot be promoted by nutrition or health claims. This means that

¹⁵⁵⁷ Nutrition claims are not discussed here as they are considered a rather simple issue where few controversies exist.

¹⁵⁵⁸ Regulation 1924/2006/EC of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

¹⁵⁵⁹ European Commission Press release IP/06/625, 16/05/2006.

health-related messages are available only to foods that are healthy as a whole. Without this rule, consumers would themselves have to calculate the health benefit of the claim and relate it to other nutritional information on the product.

However, in the final compromise version of the Regulation, it was agreed that if *one nutrient exceeds the nutrient profile*, the product could still bear a claim stating that another ‘evil’ is present in low quantities. In addition, the claim must be accompanied by a statement ‘High [...] (*) content’. This one-nutrient exception rule has been criticised for being completely unscientific, as the effect of adding one of the three evils varies greatly in different products. The loophole might lead to a situation where claims will be on products that nutritionists would not consider healthy. The original plan was that the product would always have to comply with the nutrient profile as a whole to make a nutrition claim or a health claim. The industry was opposed to this total ban, and a compromise was reached. Politics surpassed science, which sometimes happens in food law matters.

The implementation of the new Regulation is a huge job. The EFSA has the most important role as the scientific advisor. Health claims are separated in two categories:

- Health claims other than those referring to the reduction of disease risk and to children’s development and health (Article 13), so called ‘function’ claims¹⁵⁶⁰;
- Reduction of disease risk claims and claims referring to children’s development and health (Article 14).

The national food safety agencies will gather their lists of established ‘function’ claims by end of January 2008, based on which the EFSA will publish the community list of established function claims by end of January 2010. In the future, all new function claims will be scientifically evaluated by the EFSA. Disease risk reduction claims and claims related to children’s development and health will always have to be separately evaluated, and the EFSA has received applications for these claims since July 2007.

With hindsight, the chosen approach seems like the only reasonable way to deal with scientific substantiation of claims. A horizontal approach to claims¹⁵⁶¹ was established instead of creating additional product categories. The lists of already accepted claims benefit the whole business and duplicative work in substantiating claims is avoided. It is inevitable that innovative products, on which there is no scientific consensus yet, will have to go through complicated procedures.

For example Winkler has been in favour of an even simpler approach where there are only two types of claims: content claims, about what is in the food, and effect claims, about what the food does to the consumer. The operating principle for this system would be to authorise

¹⁵⁶⁰ Function claims are health claims describing or referring to:

“(a) the role of a nutrient or other substance in growth, development and the functions of the body; or

(b) psychological and behavioural functions; or

(c) without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet”. Article 13(1).

¹⁵⁶¹ The claim regulation applies to all foods irrespective of whether they are foods in food form, foods in pill form, foods for the general public, foods for certain groups of people, novel foods or GMO foods. For example, Kwak-Jukes was in favour of this approach. Kwak – Jukes 2000b, 116.

whatever claims science already substantiates and establish effective controls over the rest.¹⁵⁶² The European system is quite close to this ‘simple’ approach. Nutrition claims are the content claims, and health claims are the effect claims. It is just health claims that are separated into ‘function’ claims and disease risk reduction claims.

It was discussed above that data protection for novel food applications has been suggested in Europe. A data protection rule already applies to applications for health claim authorisation. Any food business operator may use health claims included in the Community lists, if they are not restricted for use in accordance with the provisions of Article 21 of the Regulation. Article 21 grants 5-year exclusivity to an applicant that has provided his proprietary data to support the claim.

Concerning medicines and medicinal claims, the creation of the category ‘traditional herbal medicinal product’ in 2004 manifests the European legislators’ powerless attitude as regards plant-based products. A herbal medicinal product may be sold based on ‘history of use’, where ‘history’ is defined as 30 years, 15 of which in the Community area. In the marketing of traditional herbal medicinal products, the marketer must mention that the efficacy of the product is not based on any clinical trials but instead on history of use only. Instead of an evidence-based approach, the EU decided to let the consumer decide whether to trust the product.

The category of traditional herbal medicinal products was created because there simply is no scientific proof of efficacy on several herbs that are sold in Europe. The alternatives were to require scientific proof or let the products be sold based on history of use only. The taken solution can only be temporary. The goal of foodstuffs and medicines legislation must be that there are scientific facts behind products that are used to promote health. To let herbal medicines be sold without proof of efficacy is going to harm the business in the long run. The only way to properly utilise the potential of herbal medicines is to take the scientific approach and to get rid of categories not based on clinical evidence. The Chinese are developing traditional medicine side by side with modern medicine, but Europeans certainly are not.

The same lack of science applies to homeopathic medicines. They are a similar category with traditional herbal medicines. Homeopathic medicines can be sold if homeopathic literature shows they have been used for a certain purpose. In addition, they must be diluted enough to make them safe. The marketer must mention that there is no proof of efficacy.

This situation means that herbal medicines and homeopathic medicinal products can be sold as medicines without proof of efficacy, when at the same time functional foods must have solid proof to back up their claims. Homeopathic medicines are often promoted by saying that they “are under medicines regulation”, which gives the impression that they are regulated similarly to modern medicines. Food legislation is in fact stricter science-based than medicines legislation.

In China, marketing of foods and medicines is under tightening regulatory control. The Health Food Regulation of 1996 has proven helpful in cleaning up the industry and guiding the health food market towards scientific research and development. Only health foods can bear health claims in China. The Health Food Regulation establishes 27 different functions/claims that a health food may have. Each claim has its substantiation rules listing the required animal tests and human trials to support the claim. Data protection for applicants is not granted:

¹⁵⁶² Winkler 1997, 192.

an applicant may refer to data provided by another applicant. The Chinese intend to further improve the health food registration and inspection system.

The Chinese rules on medicine marketing of 2007 aim to clean up medicine advertising mainly by two means:

- specifying the legislation: defining the prohibited marketing methods more precisely, and
- hardening punishments.

Health claim legislation was created because it was scientifically established that foods in fact have health effects. The distinction between foods and medicines is now set between disease risk reduction and disease prevention. We concluded above that in the future, the categorisation decision on whether a product is a food or a medicine might lose its significance, and that legislators should focus on safety and efficacy of all products. Efficacy would be relative to marketing, and would mean truthfulness of the marketing claims used.

It is, for example, not interesting whether lemon juice is a medicine but more interesting that it *prevents* scurvy or *reduces the risk* of scurvy. We predict that new innovations and new scientific information on health effects of foods will lead to a situation where the distinction between foodstuffs and medicines will lose its relevance, and medicinal claims will be acceptable for foods. For example, if buckthorn oil can be used to prevent the episodes of atopic eczema, it will not be relevant whether the oil is categorised as a cosmetic, a food, or a medicine. A claim will be possible if the evidence supports it. This will mean we have come full circle and the ancient adage “let your food be your medicine” is valid again.

7.4 About the Roles of Pre-Market and Post-Market Control

It is easy to agree that foodstuffs and medicines must be regulated to avoid potentially high risks to consumers. Without regulating safety, efficacy, and marketing, markets would not function properly as the consumers would not know what they were buying. Legislation is not effective unless implemented properly. This can be seen with medicine advertising in China, or marketing of weight-loss products in Europe. There are two basic alternatives on how the rules can be implemented: through pre-market control or through post-market control.

There are important differences between medicines and foodstuffs. Medicines can be precisely regulated and evaluated before they access the market, and pre-market control is thus the dominant regulatory mechanism for medicines. Pre-market control is made possible by the fact that pharmaceuticals are relatively homogenous products produced by big companies.¹⁵⁶³ In contrast to the case of medicines, strong pre-market control is usually not possible for foodstuffs. This is because the food market is much more fragmented, in China even more so than in Europe.

Before discussing official pre-market and post-market control, we must mention the control done by entrepreneurs themselves. Both in the EU and in China, the producers themselves are responsible for the safety and efficacy of their products. This means that official control does not free the entrepreneur from responsibility for faulty products. This applies both to foodstuffs and medicines. Implementation of self-control mechanisms is fundamentally a

¹⁵⁶³ Krapohl 2004, 519.

question of trust, supplemented by GMP¹⁵⁶⁴ documents and reports drafted by the entrepreneurs themselves. The self-monitoring system will save money if authorities can divide operators in separate risk categories and focus on the more risky operations, according to scientific risk assessment principles.

Pre-market control means that officials in an application must authorise a product authorised or notification procedure before it can be sold to consumers. By means of pre-market control, authorities have a chance to make sure that the product as a whole complies with the laws. A lighter version of authorisation procedure is the notification procedure, where a producer or marketer informs the authorities before bringing a new product onto the market, enabling authorities to react if deemed necessary.

There are problems to pre-clearance: gathering the necessary information into a dossier takes time and delays the placing of a product on the market. The time taken by the authorities in reviewing the product further delays market access, sometimes unpredictably. There are possible confidentiality and intellectual property issues. Pre-market control also demands public resources, unless totally funded by the regulated industry.

On the other hand, pre-market control enables broad review of products accessing the market, and will block some products that would have caused serious health incidents if used by patients or consumers. Pre-market control is also more predictable from the applicant's point of view. For this reason, entrepreneurs sometimes voluntarily discuss their product and its marketing with authorities already in the product development phase, even if there is no legislative requirement of pre-market control. The authorities sometimes take charges for these services.

At the moment, authorisation procedures are in Europe and China applied to all medicines, GMO foods, novel foods, and additives. Authorisation procedures apply also to health foods in China and novel health claims in Europe¹⁵⁶⁵. In Europe, notification procedures apply to food supplements and some of dietetic foods. The regulatory agencies of foodstuffs and medicines do not just implement the laws; they also create the law. In the pre-market procedures, the authorities often take the negotiation and counselling strategy and discuss with the applicant on how to make the product legal. Due to this practice, lawyers are not often needed to settle issues between companies and the control authorities¹⁵⁶⁶. The limits of the discussion and persuasion approach are further discussed below in chapter 7.6.3.

In Europe, safety and efficacy of functional foods will possibly in the future be evaluated simultaneously in one EFSA procedure. The separation of the two evaluations in food law is not due to any practical or scientific reasons but the two separate roots of novel food and health claim regulations. First, in the 70s, appeared foods that had previously unresolved safety issues to be dealt with. The European novel food legislation followed this technological development in 1997. Later, in the 90s, appeared functional foods where also efficacy issues had to be resolved. Legislation on health claims followed in 2007. With medicines, safety and efficacy have always been evaluated simultaneously, and now often by the EMEA. In China, safety and efficacy of health foods is evaluated in one procedure by the SFDA.

¹⁵⁶⁴ Good Manufacturing Practice.

¹⁵⁶⁵ Regulation on nutrition and health claims widened the area of pre-market control so that all new marketing claims must be authorised by the EFSA before appearance on labels and advertisements.

¹⁵⁶⁶ On the contrary, lawyers are often needed to settle issues between states protecting their own industries.

Functional foods have forced regulators to create new pre-market control mechanisms. When deciding on how to regulate functional foods, governments must weigh the benefits and costs of pre-market control. The pre-market system might be considered adequate as to safety issues, but disproportional to the possible problems of health claims. In the spirit of freedom of speech, marketing is not usually disposed under pre-market control. By misleading marketing communication, the severity of health risks caused is usually not as great as with products that are unsafe. However, it seems that regulators ended up with total pre-market control of functional foods, including their marketing. When creating new pre-market procedures, precise time limits should be given in law. This has already been done regarding pharmaceutical legislation and should also be done in the field of food law.

Today there seems to be a need for three different pre-market procedures for foods:

- 1) Innovative foods without health claims (novelty relates to other feature than health effect).
- 2) Innovative foods with health claims (functional foods).
- 3) Natural materials (mainly plants) that have not previously been used as foods.

These procedures would apply to foods in food form and foods in pill form. Procedure 1) would include additives, flavourings, and enzymes. Procedure 2) would include dietetic foods, fortified foods and GMO foods.

There is also a continuous need for two different pre-market procedures for medicines:

- 1) Herbal medicines.
- 2) Chemical medicines.

With herbal medicines, applications can be based on literature or on preclinical and clinical trials. It is questionable whether it is suitable to uphold medicine categories for products without any proof of therapeutic effect and without referral to therapeutic efficacy. Instead of creating legal categories for products on which information is not available, we could focus on scientific research to produce this information.

All of the above-mentioned five procedures would also have to include simpler versions for products that are novel but *essentially similar* to previously authorised products. At the moment, there are already simplified procedures to generic medicines and novel foods that are similar to previously authorised ones.

Even when a pre-market procedure exists, someone will always dismiss the authorisation procedure and put unauthorised products where only post-market control applies. *Post-market control* means controlling products already on the market. This means the authorities use various means to verify that product safety; efficacy and marketing are according to the law. If this is not the case, the product can be withdrawn from the market and penalties imposed.

If governments were to rely on post-market control only, the marketer of a medicine or foodstuff could basically do as he pleases but the authorities could forbid the product or marketing action afterwards. The health risks caused to consumers are the most obvious problem with this approach. This would also lead to uncertainty and waste of resources. To avoid the waste of product development and marketing efforts, companies would ask the authorities for pre-market advice on how the product would be treated. With complex issues, pre-market control is thus the only practical solution.

It is generally agreed that better post-clearance systems are needed. There are numerous problems related to post-market control of foodstuffs and medicines. ‘Wonder drugs’ are one of them. These are products claiming to cure just about everything are marketed throughout the world. Internet complicates the issue further. Responsible producers are of course against these wonder drugs, because it affects the reputation and consumer confidence in the whole business of health foods, functional foods, and herbal medicines. These ‘wonder drugs’ are not legally registered as medicines, but still marketed with medicinal claims. It is difficult to control this activity because:

- it is sometimes difficult for authorities to find the company or person that is legally responsible for marketing of the product,
- enforcement of penalties is a slow procedure because the accused can always appeal, so the marketer has plenty of time to collect cash before he can be stopped,
- the penalties for illegal marketing are not economically significant.¹⁵⁶⁷

With post-market control, legislators should focus on increasing transparencies in the food chain and the medicine industry, entrepreneur responsibility, effective implementation, and effective penalties. The issue of *burden of proof* is also important with post-market control. The burden of proof should be on the producer and marketer of a product. The entrepreneur should be able to prove the safety of his product and to substantiate the marketing claims used.

7.5 Central vs. Local Legislation

In this chapter, we discuss the competences between Central and Local legislators. In the EU, this means EU vs. its Member States. In China, this means national vs. provincial legislation. Before discussing these issues, we must discuss the relationship between global rules and the rules of EU and China. Global agreements are in a sense above both EU and China. According to the Agreement Establishing the World Trade Organization, a Member shall ensure the conformity of its laws, regulations and administrative procedures with its WTO obligations¹⁵⁶⁸.

The WTO is about negotiations, agreements, and dispute resolution. International trade rules are created through negotiations, currently the Doha round. The Dispute Settlement Body can resolve whether certain trade-related legislation passed in a national democracy is against the WTO rules. This means a WTO member state cannot legislate freely regarding protectionist purposes. WTO member states can set their own environmental or health rules, but they cannot discriminate between domestic and foreign companies. The principles of most-favoured-nation and national treatment are the cornerstones of free trade.

The WTO settles trade disputes based on trade agreements. It is not an environmental or public health organisation.¹⁵⁶⁹ However, the WTO Dispute Settlement Body cannot avoid natural science when a case is for example on a chemical and its health effects. Decisions

¹⁵⁶⁷ Enkovaara 2002, 32.

¹⁵⁶⁸ Qingjian 2002, 298.

¹⁵⁶⁹ See Palmujoki 2003, 719-720.

on such cases are often based on complex and sometimes conflicting scientific evidence¹⁵⁷⁰. To uphold WTO legitimacy, it is important to openly develop legal and scientific principles that WTO member states can agree upon. This is difficult as the interests of industrialised countries and developing countries often differ. Codex Alimentarius rules and other standards are referred to in WTO agreements. This referral makes international soft-law standards important sources of WTO law.

In Europe and China, similar trends of legal centralisation can be noticed. In Europe, the EU, not its Member States, regulates foodstuffs and medicines. In China, several national laws have been enacted since the 1990s. Where local legislation still exists, it has led to problems. The reasons for harmonisation are the same in the EU and in China: harmonisation is considered necessary in order to guarantee consumer rights, and for the proper functioning of the internal market.

Most of the important European food law has been harmonised by the EU Commission. This harmonised legislation includes hygiene rules, restrictions on additive use, pesticides and maximum levels of pesticide residues, novel food and GMO food authorisation, food supplements, food labelling and nutrition information, nutrition claims and marketing claims, etc. Food law is now frequently given in the form of Regulations instead of Directives. This is because differing interpretations are deemed to undermine the ideas of the internal market and equal consumer rights. With medicines, there is even less room for national interpretations. Medicine quality, safety, and efficacy are stipulated in exact manner by European level hard law and soft law.

European harmonisation of health-promoting foods has come a long way through regulations on food supplements, fortified products and nutrition and health claims. Areas where variations still exist between Member States are probable targets for future harmonisation. However, European national food agencies still have their various guidelines on how they interpret the European law and implement it in practice. Different practices in different states are seen as obstacles to trade. Increasing harmonisation of European food law decreases the need for both national legislation and national soft law. We predict the next issues to be harmonised in European foodstuffs and medicines law to be:

- 1) The foodstuff vs. medicine -issue.
- 2) Food supplements containing other ingredients than vitamins or minerals.
- 3) Food fortification with other substances than vitamins or minerals.

The decision on whether a product is a foodstuff or a medicine is at the moment made by EU Member States, the categorisation decisions being based on national soft law materials. This central scientific and political question is often related to functional foods, where disease risk reduction has to be compared to disease prevention. In the future, a European law on how to separate foodstuffs and medicines might be considered necessary. Simultaneously, the categorisation decision might be shifted onto the EFSA or the EMEA.

European rules on food supplements and fortified foods using for example fibre, phytosterols, or lactic acid bacteria, might be harmonised in the future. At the moment, these products are regulated by national rules. Some are also scrutinised as novel foods. Harmonisation of fortification rules would make the rules clearer for some functional food businesses.

¹⁵⁷⁰ See Kulovesi 2003, 65-66.

The size and diversity of China has led the government to use a system of local autonomy. In environmental issues, the resistance of local and provincial governments is a serious obstacle to sustainable development policy. Similar problems relate to regulation of foodstuffs and medicines. The Chinese Food Hygiene Law of 1995 declared that precise food safety standards are to be decided locally. The new Food Safety Law upholds this principle. Standards vary, and national and local standards contradict one another. Implementation and control of the rules differs among provinces and cities. The national Food Safety Standard will solve some of the problems. However, it is not possible for the central government to be aware of all the day-to-day decisions and actions of localities. Local officials might see national laws as obstacles to their cities' growth and personal promotion, and hence readily defy them. Promotions are often based on meeting economic targets, and cooperation with other provinces or cities is not rewarded. This enhances local protectionism.¹⁵⁷¹ Distrust in food and medicine marketing describes consumer attitudes in China.

An important step towards centralisation in China is that currently all food and medicine pre-market authorisations are under the competence of the SFDA. This has eliminated the conflicting standards that previously prevailed among provincial government agencies. The Health Food Regulation was important in setting common national rules for functional food products. The proposed national law on traditional herbal medicines will strengthen patient confidence in China, and also promote acceptance of herbal medicine and related business opportunities in foreign countries. In the future, China will probably have to harmonise all important food and medicine standards nationally in a similar manner that is being done with exported foods. Chinese laws as such already guarantee that foodstuffs and medicines are safe and effective. As stated above, China can build confidence in the food and medicine industries by strengthening *implementation and control* of laws, and particularly at the local level.

In Europe, there have been complaints that it is difficult to understand the totality of Community and national laws. For example, the Finnish Ministry of Agriculture and Forestry has stated that "the totality of foodstuff legislation will inevitably be unclear", because European regulations are not repeated in the Finnish law¹⁵⁷². European law both *adds volume* and *complicates structure*. Hallberg states this from a court's perspective¹⁵⁷³. Likewise in China, the relationship of national laws and local laws is not clear. Laws are often broad and hard to understand as such. In China, national and local laws at times contradict one another, and national government agencies have to take action to revoke local laws¹⁵⁷⁴.

There are solutions to complexity stemming from central vs. local laws. The obvious solution is abolishing local laws. The European approach is not in fact far from this situation. Central regulation would guarantee equal consumer and patient rights, and also free movement of goods. However, there are also positive sides to local legislation. The most persuasive argument in favour of local legislation is that it is easier for citizens and local experts to get their voice heard. It does not serve any purpose to enact the same laws both on central and local level. The local laws must serve local needs and be based on genuine local differences in these needs.¹⁵⁷⁵

¹⁵⁷¹ Lam 2006.

¹⁵⁷² Maa- ja metsätalousministeriö. Selvitys lainsäädännön muutostekijöistä 2005. Page 13.

¹⁵⁷³ Hallberg 1997, 69.

¹⁵⁷⁴ Lam 2006.

¹⁵⁷⁵ See Tala 2005b on the role of national legal policies.

If both central and local legislation are considered necessary, regulation targets can be served by using a referral technique, where local laws refer to central laws. In China, implementation and control of central laws must be enhanced. This will require a culture where pursuing national aims is awarded instead of pursuing local aims. Also in Europe, national and local favouritism can sometimes be detected behind food and medicine law. European laws are still often compromises between national interests rather than instruments based on scientific risk analysis and common economical goals.

As opposed to minimum harmonisation, maximum harmonisation is today preferred in EU consumer protection. Simultaneously, it seems that the focus has shifted from the consumer onto the entrepreneur. First, consumer protection was primarily about protecting the consumer. Now the goal rather seems to be to keep the protection at a reasonable level to facilitate trade. For example, the UCP directive tries to make the rules on consumer marketing clear, as national rules cease to exist. Simultaneously, positive aspects of diversity might be missed. Nehf suspects¹⁵⁷⁶ that at least in the short term, the UCP Directive might increase legal complexity rather than simplify the rules. According to him, simple solutions often fail to fix complex problems.

MacMaoláin (2007) is of the view that national regulators would, more likely than the EU Commission, pay attention to food quality such as nutritional properties (for example to fight obesity) and ethical questions. He thinks that in order to promote free trade, the EU sets unnecessarily low requirements on foods. According to the industry on the other hand, food safety and food quality should be strictly separated into area of law (safety) and area of markets (quality). This would mean leaving the quality dimension of foods for the consumers to decide: consumers will pay for the quality they want. We are of the view that consumers need encouragement by legislators. Products should be legally favoured if they are healthy for people and the environment and also ethically sustainable.

7.6 About the Role of Soft Law

7.6.1 Types of Soft Law

In Europe, there are at least four different types of soft law concerning food and medicine industries:

- 1) Administrative regulations and so called normative and scientific guidelines by the Commission, the EFSA¹⁵⁷⁷, the EMEA¹⁵⁷⁸ and national food and medicine agencies.
- 2) Standards by governmental organisations such as Codex or Council of Europe.
- 3) Standards of non-governmental organisations, for example the International Life Science Institute and consumer organisations.
- 4) Self-regulation guidelines.

¹⁵⁷⁶ Nehf 2007.

¹⁵⁷⁷ European Food Safety Authority.

¹⁵⁷⁸ European Medicines Agency.

In China, it is difficult to separate between hard law and soft law. First of all, there are laws enacted by the National People's Congress. Then there are regulations and directives given by the State Council, which is the highest administrative body in the nation. In reality, it is the State Council that decides on important law. In addition, there are regulations and directives given by various departments under the State Council. These departments include the Ministry of Health and the State Food and Drug Administration.¹⁵⁷⁹

7.6.2 Administrative Soft Law and the Role of Regulatory Agencies

Various administrative guideline-type documents are particularly important in regulating foodstuffs and medicines. There are several reasons for this:

- There is a need for *scientific expertise*. Several issues are resolved by scientists alone.
- There is a need for great regulatory *detail*. Requirements on product safety and efficacy cannot be defined in flexible terms because these may become a matter of life and death or serious impact on health. This applies most of all to the pre-market authorisation procedures. The large amount of detailed rules means large volumes of guidance texts.
- There is a need for *constant changes*, due to the scientific and detailed nature of the laws.

Administrative soft law is considered a necessary and a natural part of medicine law. In a 2002 WTO publication, it is stated that medicine laws provide the basis for medicine regulation, but standards and guidelines equip regulatory authorities with the *practical means* of implementing the laws. The absence of soft law guidelines “may lead to variations in the implementation of the law, or even lead to questions about the transparency of law enforcement”. Therefore, “standards and guidelines should be established in a written form for all medicine regulatory functions”. Administrative soft law should be publicly available to all the parties involved, and be used to guide regulatory practice.¹⁵⁸⁰ For the same reasons, soft law guidelines are needed in the food industry: besides the applicants, guidelines tell the authorities themselves how to lead the application procedures.

Senden recommends that European soft law instruments should be rationalised and used consistently, and that their legal effect should be clarified¹⁵⁸¹. The Commission has worked to clarify the role of guidelines in the field of medicines law¹⁵⁸². The main conclusion is that although not binding, guidelines should be followed unless there is good reason to deviate from them. European soft law on medicines is given mostly at the Community level. The ‘Notice to Applicants’ by the Commission is an important source of law defining the details of the pre-market authorisation process of medicines. The Notice includes regulatory guidelines. Scientific guidelines by the EMEA specify the requirements for tests and trials on medicines. These documents are not legally binding but are, in practice, followed like laws.

¹⁵⁷⁹ Lists of Chinese food, drug and cosmetics laws in 2007 at: http://www.chinafdc-law.com/laws/index_1.html.

¹⁵⁸⁰ Ratanaqijitrasin – Wondemagegnebu 2002, 2.

¹⁵⁸¹ See Recommendations by Senden 2004, 498-502.

¹⁵⁸² Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework. London, 20 June 2005. EMEA/P/24143/2004.

Efforts to clarify the role of soft law would be welcome also in the food sector. Namely, soft law is also important in European regulation of foodstuffs. With novel foods, the Commission Recommendation is particularly important. The Recommendation defines the requirements and details of the European pre-market procedure that applies to novel foods¹⁵⁸³. A pre-market procedure applies also to GMO¹⁵⁸⁴ foods. In this case detailed rules were given by the Regulations themselves¹⁵⁸⁵, not by a Notice or a Recommendation. This might have implied that a preference for legally binding instruments was emerging. However, with the Health Claim Regulation, the application procedure is again based on guidelines by the EFSA.

Large volumes of soft law materials regulating foodstuffs are given also by EU Member States. For example, the Finnish food agency has their guidelines on practically every issue where legal uncertainty might arise. These guidelines not just explain the law but create it. The Finnish regulatory guidelines include, for instance, a guideline on food supplements, where detailed information on separation of herbal medicines, food supplements and dietetic foods is included. It is stated that to be classified as a food supplement, a product can provide at most 200 kJ energy per day. This information is nowhere else to be found. The UK Food Agency has created a complete regulatory package on so-called borderline products that are either medicines or foods. A particular problem with European national guidelines is that they are *not always translated to any other European languages*. It is thus difficult for entrepreneurs in other European countries or third countries to be aware of their contents. Crucial information could be missed that might even affect the decision on whether to bring the product to the market in the first place.

A general problem with international and national guidelines is that *the procedure for drafting them is not always democratic or transparent*. Guidelines are often discussed among the stakeholders, but there are no rules on who will be asked for opinion and whose opinion weighs the most. When factually delegating legislative power to food or medicine agencies, one must carefully consider who actually makes the decisions and whether common good will be pursued. The capacity and expertise of the agencies must be such that the industries cannot outweigh them.

Another basic legal problem with these guidelines is that entrepreneurs and consumers *cannot appeal these guidelines as such*. Guidelines are something between legislation and administrative decisions implementing the law. Guidelines do not possess the democratic element of legislation, and neither are they subject to control by courts. Legally, the binding nature of guidelines is difficult to grasp. Soft law guidelines tell regulation objects how the legislation will be interpreted when decisions in individual cases are made. The makers of soft law guidance documents are not assuming any responsibility on whether they are interpreting the laws correctly. If an entrepreneur decides to follow a guideline, he still cannot be sure of

¹⁵⁸³ With novel foods, companies that want to place a novel food on the EU market need to submit their application in accordance with Commission Recommendation 97/618/EC that concerns the scientific information and the safety assessment report required.

¹⁵⁸⁴ Genetically modified organism.

¹⁵⁸⁵ Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, supplemented by Commission Regulation (EC) 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

doing everything correctly. However, following guidelines will probably be seen at least as a bona fide attempt to follow the law. Not following guidelines will be seen as something an entrepreneur will have to explain. This way, *guidelines can be seen as a starting point for discussion*.

If we want to create law that can be trusted, and rights and obligations that can be enforced, soft law should not be created. In this case, the Commission, the EFSA, the EMEA, and all the national agencies should be given the legal competence to do what they are already doing: giving more detailed regulations on general food and medicine laws. In this case, they would not have to use phrases like “this is not a complete or definitive statement of the law”. This extensive delegation of hard legislative power does not seem acceptable. In spite of the ambiguity, we might be more comfortable with non-binding soft law.

Non-binding guidelines are in fact a part of an implementation strategy where agencies have a lot of power and implementation is based on co-operation, flexibility, and negotiation. Guidance by guidelines is supplemented by individual guidance given by agencies to targets of regulation. Implementation happens through constant interaction between entrepreneurs and the implementing agencies. Business operators often ask the foodstuff and medicine agencies for information on how to fulfil their legal requirements, and the agencies explain - and create - the law as best they can. Persuading the regulation targets to follow the rules is often cheaper and faster than forcing them to follow the rules. Using sanctions might spoil the cooperation spirit.

The cooperation strategy has its limits, though. First, *this kind of implementation strategy can only work when regulation targets are motivated to follow the rules*¹⁵⁸⁶. Getting caught selling products that are hazardous to health will have a strong impact on company image for years. For this reason, most food and medicine companies are completely willing to try their best to avoid this. ‘Normal’ food industry operators and pharmaceutical companies are responsible, or at least interested in their responsible image.

However, sometimes business operators will not listen to any non-binding guidance or persuasion. All kinds of ‘magic’ foods and food supplements marketed for weight loss both in Europe and China can be mentioned as examples. These products are continuously marketed with false and misleading claims, and the agencies must use sanctions to get them off the markets. For these companies, short-term financial gains are more important than long-term credibility.

Secondly, there is the risk of so-called *regulatory capture*, where the objects of regulation push their demands so far that they actually get to decide how they are regulated. Agencies must be careful of not giving too much weight on the industry opinion only. Cooperation and mutual understanding does not mean that the agencies must always please the industry. It merely means that, if possible, industry efforts are recognised, and overly burdensome measures are avoided.

The third important challenge of the strategy is *treating entrepreneurs equally*. The use of non-binding guidelines and case-by-case information guidance means that implementation is flexible in a certain meaning. This brings the negotiation element into the picture. The entire information and negotiation strategy is based on trust, and it will lose its foundation if implementation takes place on unequal terms. Flexibility cannot mean that companies with similar risks are treated in a different manner. Equal treatment is the responsibility of the

¹⁵⁸⁶ Tala 2001, s. 271.

agencies. Ethical rules and implementation principles must be discussed among agency staff. In the supranational context, the decision-making rules are even more important.

Scientific risk assessments and scientific guidelines are the most suitable tasks for foodstuff and medicine agencies. Independent agencies are valuable in resolving scientific issues based on science, not politics. If we want the EMEA and the EFSA in Europe and the SFDA in China to perform impartial risk assessments based on science, we must guarantee independence from political actors. This is because it is often tempting to pursue local short-term interests instead of common good, particularly if everybody else is doing the same. Trust in other European nations is needed for the Europeans to allow the agencies to act independently. Likewise in China, the SFDA needs its independence to be credible.

Creating total independence of the agency (EMEA, EFSA, of SFDA) creates a control problem, as the agency might develop a will of its own. The control problem can be avoided by setting *substantive decision-making criteria by law*, in which case it is possible to subject decisions of regulatory agencies to review by courts. This is what Krapohl suggests¹⁵⁸⁷. This means the political actors must set the legal principles under which the agency acts. Only after this can implementation be trusted within a regulatory agency.

7.6.3 Standards

Standards are seen as playing a supporting role to legislation. The European Commission sees standards as “technical specifications which allow compliance with legal requirements”. Standards are seen as innovation-friendly, as they are developed by the interested parties themselves and updated according to state of the art.¹⁵⁸⁸ The European Commission sees standards as the New Approach to legislation that allows public and private interests to merge, at the same time fulfilling the goals of Better Regulation. The Commission has in 2008 re-asserted its commitment to market-led standardisation and to the voluntary use of standards¹⁵⁸⁹.

Even though standardisation is presumed as private action, governments are involved. Standardisation is thus something between public and private. The European Commission says “A stronger role for standardisation ... is important for the ... effort to address economic, environmental and social challenges.” If we look at these goals, it sounds like standards are the new law. Standards, particularly global standards, are seen as the new approach saving governance from its oblivion created by the fall of the nation-state. Standards are seen as a “better-regulation” alternative to legislation, and an answer to many of the problems in modern societies.

Using standards does not free us from questions of regulation quality, critical evaluation, and further development. *How* regulation is done is more important than *who* does it. Standard setting is a procedure: what is important to regulation targets is the outcome of this procedure, the *content* of the regulation. Regulators need to let stakeholder voices be heard, balance interests, be just.

¹⁵⁸⁷ Krapohl 2004.

¹⁵⁸⁸ Commission Communication on Standards 2008, 4.

¹⁵⁸⁹ Commission Communication on Standards 2008, 6.

4.6.4 Self-Regulation

As an alternative to legislation, regulators should consider the viability of self-regulation or industry codes of best practice. Some of food and medicine law issues might be better resolved by the industries themselves. Reliance on self-regulation should always be the result of a conscious process by the government, where the benefits and downsides of self-regulation have been weighed. Self-regulation should not exist just because the legislator is too busy to react on some issue, the legislator wants to get the easy way out, or just because the industry claims that legislation is not welcome.

There is more space for self-regulation in the foodstuffs sector than with medicines. The pre-market authorisation process for medicines is globally harmonised and very strictly defined by law without much room for interpretation. In Europe, the Commission and the EMEA have drafted all the necessary explanatory documents. Self-regulation is mainly related to advertising of medicines. Likewise in China, self-regulation does not have a great role in regulating medicines.

Regulation of foods is heading for the same direction: the food industry is getting more and more regulated. New food legislation covers new areas and is also stricter than before. This development is due to serious health problems that have received wide attention and created consumer distrust. Legislators see their job as building confidence in new products such as functional foods. They have, for example, created pre-market authorisation processes for novel foods and precise criteria for presenting health claims.

The food industry is not content with tightening regulatory control. They demand that the area of self-regulation is expanded. They claim to be responsible and willing to guarantee consumer rights themselves. However, they have not in practice addressed the issue of high-energy food marketing to children, for example. Advertising restrictions imposed in Britain were considered too demanding because “they might affect sales”. It is not likely that business operators will pass rules on themselves if there is a financial cost to it. Even if the majority of food industry actors were to agree on the rules, there would always be some players breaking the codes and destroying the system.

The Chinese government has in food hygiene issues promoted self-regulation and regulation by consumer organisations. The Chinese are also campaigning to make consumers more responsible with regard to food safety issues. Although important, these approaches will not suffice. In China it is an enormous task to officially control the whole food chain, so the government wishes that food business operators and consumers could manage by themselves. In our opinion, the laissez-faire attitude will not work in China or in Europe. Foodstuffs and medicines are too important for the government to step aside. Self-regulation has proven useful in certain minor questions where the industry as a whole is motivated in following common rules that often supplement hard-law norms.

Consumers often prefer legislation to self-regulation, based on experience. Consumer demands in product safety and marketing information are in practice always opposite to the industry propositions. Perhaps consumers are trying to get more than they actually want in order to get at least something. Consumers often ask for things that they don't actually need, and certainly don't want if there is a cost to it. They also ask for things that are certainly not good for them. Consumers are often ignorant, indifferent, or even self-destructive. Just like the industry opinion, the consumer opinion cannot be the only decisive one when deciding on food and medicine law.

If we decide to keep creating soft law, we need to discuss the legal weight of this material. There will be no simple answer to the question. Different parts of soft law should have different weight. If a document comes from “a regulatory agency”, an average citizen will understand it being the law. There are legal certainty reasons that support giving weight to regulatory agency guidelines. Self-regulation is different, as an entrepreneur knows he is here not dealing with law. The courts do not have to consider that abiding by the industry norms is always adequate. The industry norms might not be strict enough, as businesses are not often the first to impose norms upon themselves. There might be important considerations that have been totally left out of the industry norms. However, following the industry norms can still be used as evidence of bona fide efforts to act legally, especially where ‘hard law’ norms are missing.

7.7 Final Conclusions

The main tasks of legislators regarding foodstuffs, medicines, and functional foods are in our opinion:

- A) *To ensure that products on the market are safe and effective.* This requires focus on implementation and control. There have to be standards on required scientific studies to prove safety. Hoax products should be taken off the market in order to build trust in products that actually work.
- B) *To create a favourable environment for research and development.* This includes providing proper education in natural sciences, offering support to R&D firms in their research projects, strengthening cooperation between universities and companies, and establishing adequate intellectual property protection.
- C) *To guarantee adequate information* on foodstuffs, medicines, and functional foods by raising public awareness on diet-health issues by means of health education, and by ensuring that only understandable and useful marketing claims are used.
- D) *Possibly to further encourage healthy consumer behaviour* such as giving tax benefits for healthy products, or restricting advertising, or even sales, of foods that are high in calorific value, fat, salt and sugar. Financial rewards for healthy lifestyles have been suggested as an even more extreme incentive.

With foodstuffs, medicines, functional foods as we defined them, and functional foods as others define them, the primary task of regulators is *to promote health*. Regulation will have an effect on the *dietary and medical choices* of consumers. Functional foods have to be judged by their merits. The ultimate aim of regulation on functional foods should be to make consumer diets better and the amount of patients smaller. European and Chinese regulators cannot work alone to achieve this. As members of the WTO, they cannot decide to promote their industries and protect their citizens simply by dismissing foreign products. Food law and medicine law issues are better solved globally and international cooperation is integral.

When regulating functional foods, the restrictive approach of protecting consumers is not enough. The governments must look at functional foods as a positive development. New healthy products coming to market and a wide selection of choices benefit consumers. Besides health effects, functional foods can be valuable in offering business possibilities also for smaller companies and creating jobs. The governments must thus aim at regulatory solutions

that promote innovation and do not stifle competition. The appropriate level of intellectual property protection needs to be carefully considered. The legislators must set clear, enforceable requirements and predictable, transparent procedures. Many governments have promoted food development also by allocating public research funds into food development.

The concepts of ‘food security’ and ‘right to food’ have changed over time¹⁵⁹⁰. Food security means that food is available and that it is safe. Law can potentially play an important role in both¹⁵⁹¹. Today food security is not just understood as a right to sufficient food, but as a right to safe, nutritious, and healthy food¹⁵⁹². Functional foods might further widen the concept of food security. A person might, for example, be considered to have a right to use cholesterol-lowering foods. Here the task of governments and other governance regimes would be to ensure consumer access to safe and effective products. The WHO Nutrition report of 2003 recommends the creation of “health-supporting environments”. It is not a question of communities vs. governments or local initiatives vs. legislation. Both are needed. Consumers and food chain operators need to be involved.¹⁵⁹³ Administrative regulations, standards, and self-regulation are new modes of governance that have profound implications on how law and democracy are perceived.

A lot of energy is currently being used to settle whether a product is a food or a medicine. This is particularly with plant-based products such as berries and herbs. The governments must look at the use of foodstuffs and medicines from a new perspective. Foods and medicines may well be used for similar purposes. This means *food law and medicine law should be considered as a whole*. The division of foodstuffs and medicines would lose its significance if food law and medicine law were to be merged with each other. According to Howe, it is time to break down the somewhat arbitrary regulatory barriers that discriminate between foods used for sustenance alone, functional foods, food supplements, traditional or herbal medicines, other over-the-counter products and prescription medicines. Manufacturers, health providers and consumers would be better served by establishing a unified approach for evaluating the health potential – and limitations – of all these products¹⁵⁹⁴.

We could aim at developing a range of integrated diet and lifestyle options for achieving and maintaining optimal health. If treatment was necessary, we could use the most efficacious combinations of active nutrients with medication. Obvious examples are the use of low-fat diets with cholesterol-lowering drugs and low salt foods with blood pressure medication. However, medicine companies are not currently encouraged by the regulatory environment to evaluate the potential benefits of nutrient/medicine combinations. Adoption of such a combination approach will require an unprecedented level of cooperation between the regulatory authorities and all stakeholders.¹⁵⁹⁵

In addition to international fora, *more discussion on food and medicine law is needed* on national, local, and consumer level. An average consumer would probably want food and medicine law to promote health but also to guarantee information and freedom of choice. Part of consumers might want the law to promote sustainable development. In a democracy,

¹⁵⁹⁰ Mechlem 2004, 647-648.

¹⁵⁹¹ Snyder 2004, 496.

¹⁵⁹² Mechlem 2004, 648.

¹⁵⁹³ WHO Nutrition Report 2003, 144.

¹⁵⁹⁴ See Howe 2000, S111.

¹⁵⁹⁵ See Howe 2000, S111.

citizens can vote representatives to change the laws if they wish. However, food and medicine law is not often familiar to consumers, and the issues are not debated before elections. If questioned, European consumers and citizens might have differing opinions, for example, on the following European legal solutions that currently exist:

- generic copies of originator medicines can be sold after 10 years has passed since authorisation of the originator medicine,
- herbal medicines can be sold without proof of efficacy, even if they have a relatively short history of use in Europe,
- even thousands of year history of use in third countries does not allow a herbal medicine to be sold in Europe,
- homeopathic medicines can be sold without proof of efficacy,
- old foods are presumed safe, and new foods are presumed safe if they are similar to old foods,
- third country old foods such as vegetables and berries are presumed unsafe and it is thus difficult to bring them onto the EU market,
- innovative foods are presumed unsafe and it is thus difficult to bring them onto the EU market.

What is relevant regarding consumer law is what the consumers expect of the law. The *culture of trust* in a regulated market affects expectations on how cautiously one needs to act on the consumer market. European consumers appear to expect the state to safeguard their position in the marketplace. However, even the legal cultures in Northern and Southern parts of Europe differ in this respect.¹⁵⁹⁶ American consumers tend to trust collective consumer activism rather than consumer law¹⁵⁹⁷.

Even though Chinese legal rules and institutions are increasingly similar to their Western counterparts, legal culture will change slowly¹⁵⁹⁸. The Chinese tend to trust neither the law nor the companies. In China, the difference between legal system surface and legal reality is a wider cultural phenomenon. It is related to the notion of ‘rule by man’, the reliance to family and friends in the first place, and the Confucian principle of conflict avoidance. In the Chinese legal culture, the administrator long had all the (imperial) power. The ‘rule by man’ tradition runs counter to rule of law. The separation of powers is new to the Chinese and reliance to social connections, *guanxi*, is deeply rooted and also runs counter to the establishment of rule of law¹⁵⁹⁹.

¹⁵⁹⁶ Consumers in Northern Europe expect to be protected at the level of institutions and programs,

^whereas consumers in Southern Europe rely on personal contact with the seller, Howells et al. 2006, 257.

¹⁵⁹⁷ Business ethics as science, as corporate culture, and as brand strategy developed in the U.S. because legislation was too slow and ineffective in reacting to clear ethical problems in corporate behaviour. Regulation is in the U.S. often used only when absolutely necessary, freedom being a core value. This relates to the history of the U.S. as a British colony and the federal government as a representative of this colonial power. See Tolonen 2007.

¹⁵⁹⁸ According to Jones, Chinese legal system may some day be what it now is on paper. He suspects this will not happen soon, if ever. He thinks the surface will be similar to Western legal systems, but the legal culture will continue to be influenced by history. Jones 2003, 40.

¹⁵⁹⁹ Kubayashi 2008, 6.

Legal culture, including consumer trust in regulation, is not a stable phenomenon but changes through time. The roles of governments and other governance regimes are constantly in flux. Consumers will have to learn the most basic assumptions on a given legal culture:

- what can be expected of regulators,
- what can be expected of companies, and
- what is under their own responsibility.

From a consumer viewpoint, there is not a substantial difference between who regulates the companies: whether it is governmental bodies or non-governmental bodies. From business viewpoint, there is a difference between law, co-regulation and self-regulation. As the scope of business law widens, the room for business ethics becomes narrower, and vice versa: if business ethics are highly developed, law is supposedly not needed.

Confucius relied on moral rather than legal rules. Currently rule of law is gaining importance in China. Reverting to legal proceedings is new in China and something that Confucius wholeheartedly avoided. Legal institutions are needed because of the transition from planned economy to market economy. This transition is not complete, which makes it difficult for the Chinese and others to know the roles of state vs. markets in China¹⁶⁰⁰. According to Qingjiang, there is no turning back China's progress into a market-oriented economy and rule-based society¹⁶⁰¹. At the same time, rule of law is being discussed in Europe, as legislation is increasingly replaced by co-regulation, standards, and self-regulation. A new understanding of law is emerging. When China accepts rule of law, *rule of law as we know it may no longer be the same*.

¹⁶⁰⁰ See Lichtenstein 2003, 288, about corruption and the unclear role of the state.

¹⁶⁰¹ Qingjiang 2002, 62.

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